EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

PLAINTIFF'S EXPERT REPORT OF AMIRALI Y. HAIDRI, ESQ. RESPONSIVE TO AND IN REBUTTAL OF DEFENDANT'S OPENING EXPERT REPORT OF MANSOOR M. AMIJI

RESPONSIVE EXPERT REPORT OF AMIRALI Y. HAIDRI, ESQ.

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D Portion from a Clinical Study Report dated March 7, 2012, titled, "A Multi-Center Study to Determine The Safety and Efficacy of Trutek's 'Multi Acting Particle Blocker (MAPB)' as a Preventive Treatment for Cold and Flu."

E USPTO Office Action dated August 25, 2011 concerning U.S. Patent Application Serial No. 12/467,271 (Wahi) constituting a non-final rejection of all claims for lack of enablement.

F Claims 1 and 2 of U.S. Patent Application Serial No. 12/467,271 (Wahi) as originally submitted to the USPTO on May 16, 2009.

G USPTO Office Actgion dated November 9, 2005 concerning U.S.Patent Application Serial No. 10/458,078 (Rolf) constituting a non-final rejection of all claims for obviousness double patenting, lack of enablement, anticipation by and obviousness over the prior art.

H U.S. Patent No. 6,090,403 issued to Block, *et.al.*, on July 18, 2000.

I U.S. Patent No. 6,844,005 issued to Wahi, *et.al.*, on January 18, 2005.

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TERMS OF ENGAGEMENT

TRUTEK Corp.
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Gentlemen:

You have engaged my services as a technical expert in the matter of Trutek Corp. *v.* BlueWillow Biologics, Inc., currently in litigation in the Eastern District of Michigan, Southern Division, Civil Case No. 2:21-cv-10312-SJM-RSW. You allege that BlueWillow Biologics, Inc. ("BlueWillow") infringed the claims of your U.S. Patent No. 8,163,802 (hereinafter, "the '802 Patent").

I am an attorney licensed to practice in the States of New Jersey and New York, and I am licensed as a patent attorney at the United States Patent and Trademark Office. I obtained my undergraduate degree in chemical engineering in 1971 and a master's degree in organic chemistry in 1983. I have been a practicing patent attorney since 1982. My resume is attached hereto as Exhibit A.

I read and understood the specification and claims of the '802 Patent. I also read and understood the opening expert report by Mansoor M. Amiji on invalidity of the '802 Patent and the accompanying exhibits. My first assigned task is to provide a rebuttal report. You have also requested that I provide testimonial evidence in rebuttal to BlueWillow's allegations of patent invalidity.

My current fee for services is $350 per hour. I will be entitled to receive reimbursement for travel and out-of-pocket expenses related to this engagement.

Amirali Y. Haidri, Esq.

II. FINDINGS AND CONCLUSIONS

Having reviewed BlueWillow's opening expert report by Mansoor M. Amiji (the "Amiji Report") along with its exhibits and other relevant materials, I formed the following opinions:

1) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101.

2) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of credible utility.

3) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of enablement.

4) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of adequate written description.

5) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wahi '488 or in combination with Rolf.

6) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wadstrom alone, or in combination with Rolf.

7) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 alone or Baker '476 alone, or in combination with Rolf, or Khaled, or Rabe, or Katz, or Wahi '790.

III. RELEVANT PATENT STATUTES

A. 35 U.S.C. § 101 - Inventions Patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The invention must be new and useful. An issued patent is presumed valid, and this includes a presumption of validity. *Structural Rubber Prods. Co. v. Park Rubber Co.,* 749 F.2d 707, 741 (Fed. Cir. 1984).

B. 35 U.S.C. § 102(a) - Conditions for Patentability; Novelty

NOVELTY; PRIOR ART — A person shall be entitled to a patent unless —

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

35 U.S.C. 102(a) refers to claim anticipation. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 (Fed. Cir. 1987).

C. 35 U.S.C. § 103 Conditions for patentability; non-obvious subject matter.

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill

in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

> Obviousness is a legal conclusion. *E.g., Aktiebolaget Karlstads v. United States ITC*, 705 F.2d 1565 (Fed. Cir. 1983). It is a question of law to be determined from the facts. *In re. Geiger,* 815 F.2d 686 (Fed. Cir. 1987); *in re. Blauwe,* 736 F.2d 699 (Fed. Cir. 1984). "Whether an invention would have been obvious in terms of §103 is ultimately a legal judgment, dependent from the factual evidence adduced." *Burlington Indus. Inc. v. Quigg,* 822 F.2d 1581 (Fed. Cir. 1987).

D. 35 U.S.C. § 112 Specification

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

> Enablement means that practice of the invention must not require undue experimentation, although reasonable experimentation by a person having ordinary skill in the art is permitted. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d 788 (Fed. Cir. 1985). The enablement requirement is met if the description enables any mode of making and using the claimed invention. *Engel Indus., Inc. v. Lockformer Co.,* 946 F.2d 1528 (Fed. Cir. 1991). The best mode requirement is a subjective test in that it requires a disclosure only of that which the inventor (not someone else) contemplates as the best way of carrying out the invention at the time. There is no duty for an inventor to disclose details of which he or she was not aware. *Gargoyles, Inc. v. United States,* 113 F.3d 1572 (Fed. Cir. 1997).

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

(c) FORM.—A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

> (d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in independent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.
>
> (f) ELEMENT IN CLAIM FOR A COMBINATION.—An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

E. 35 U.S.C. § 282(a)

> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

IV. THE CLEAR AND CONVINCING STANDARD OF PROOF

In *Microsoft Corp. v. i4i Limited Partnership,* 564 U.S. 91 (2011), the U.S. Supreme Court held that 35 U.S.C. § 282 "requires an invalidity defense to be proved by clear and convincing evidence." Such evidence requires a higher standard of proof than proof by a preponderance of the evidence.

"'Clear and convincing evidence' is that weight of proof which produces in mind of trier of fact a firm belief or conviction as to truth of the allegations sought to be established; it is evidence so clear, direct, weighty and convincing as to enable fact-finder to come to clear conviction, without hesitancy, of truth of the precise facts of case." *In re CNC Payroll, Inc.*, 491 B.R. 454, 461 (2013), citing *Shafer v. Army & Air Force Exch. Serv.,* 376 F.3d 386, 396 (5th Cir.2004). See also, *In re JMW Auto Sales*, 494 B.R. 877, 889 (2013).

In the United States Patent and Trademark Office (USPTO), when examining a patent application prior to a patent grant, the lower standard of preponderance of the evidence is used. Patent examiners are intimately familiar with patent law, and they routinely interpret proposed claims in light of the inventor's disclosure. Examination of patent applications is delegated to specific art groups employing examiners that deal only with the subject matter of the particular invention. The examination of patent applications prior to issue is rigorous. However, according to 35 U.S.C. § 282(a), patents once issued are presumed valid. Thus, the decisions of the USPTO leading to a patent grant are given great deference.

An applicant for a patent is required to disclose any information known to him that is material to patentability of his invention. This duty is codified in 37 CFR § 1.56, (*viz.*, Duty to disclose information material to patentability). This regulation applies to "applicants and other individuals substantively involved with the preparation and/or prosecution of the application." The disclosure is accomplished by applicant's submission of an Information Disclosure Statement ("IDS"). MPEP[1] § 609. An applicant "also may want the Office to consider information for a variety of other reasons; e.g., to make sure that the examiner has an opportunity to consider the same information that was considered by these individuals, or by another patent office in a counterpart or related patent application filed in another country." *Id.*

With regard to the present matter concerning the '802 Patent, the applicant submitted an IDS, which is attached hereto as Exhibit B. On August 19, 2011, Examiner Raymond Henley III, considered and initialed all of the prior art references submitted by the applicant. This initialed document is attached hereto as Exhibit C. From that initialed document, it is apparent that Examiner Henley considered the following prior art references:

- US Patent No. 5,468,488 issued to Wahi on November 21, 1995 ("Wahi '488");
- US Patent No. 5,674,481 issued to Wahi on October 7, 1997 ("Wahi '481).
- US Patent No. 6,844,005 issued to Wahi on January 18, 2005 ("Wahi '005").
- US Patent Application Publication No. 2003/0223934 published on December 4, 2003 ("Wahi '934").

[1] The term "MPEP" is an acronym for the Manual of Patent Examining Procedure published by the USPTO and intended to instruct patent examiners how to examine applications for patentability.

The Wahi '005 patent issued from U.S. Patent Application No. 10/082,978, which was filed on February 25, 2002. That application was published by the USPTO as US Patent Application Publication No. 2003/0161790 ("Wahi '790"). The specifications of Wahi '790 and Wahi '005 are identical. Thus, Examiner Henley was aware of the teachings of Wahi '790 during prosecution of the '802 Patent. The Amiji Report cited prior art references Wahi '488, Wahi '481, and Wahi '790 to prove invalidity of claims 1, 2, 6, and 7 of the '802 Patent. These three references must be given special deference because they were considered by the USPTO prior to issuing a Notice of Allowance. Under a clear and convincing standard, it is a finding of fact that should be overturned only upon a finding that no reasonable examiner would have allowed the claims in light of the considered prior art.

In *Microsoft* 564 U.S. 91, the Supreme Court rejected "Microsoft's argument that a preponderance standard must at least apply where the evidence before the fact finder was not before the PTO[2] during the examination process." The Court held that the proof of invalidity must be by a clear and convincing evidentiary standard regardless of whether the USPTO previously considered the evidence of prior art.

[2] The acronym PTO means Patent and Trademark Office. It is an equivalent designation to the acronym USPTO used elsewhere in my report.

V. STANDARDS FOR INQUIRY INTO PATENT INVALIDITY

For an application to issue as a patent, the USPTO must determine that the issued claims meet all of the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Only where clear and convincing evidence is presented that a claim fails to meet any of these requirements may that claim be deemed invalid.

A. 35 U.S.C. § 101

> *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

35 U.S.C. §101 defines what types of inventions are eligible for patent protection, more commonly referred to as statutory subject matter. The scope of inquiry into the statute is:

- eligible subject matter,
- utility, and
- novelty.

1. Subject Matter Eligibility

Eligible subject matter comprises a process, a machine, a manufactured article, and a composition of matter. A process claim is synonymous with a method claim, which is a series of steps that a person of ordinary skill must perform. A formulation may be both a manufactured article and a composition of matter.

Judicial decisions stated that non-man-made inventions are not patentable. For example, "[t]he laws of nature, physical phenomena, and

abstract ideas have been held not patentable." *Diamond v. Chakrabarty,* 447 U.S. 303, 309 (1980). Thus, Einstein's theory of relativity and Newton's law of gravity are ineligible. *id.* These are "manifestations of ... nature, free to all men and reserved exclusively to none." *Funk Bros. Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127, 130 (1948).

The first step for the USPTO in examining a patent application is to determine whether the subject matter of the invention is allowed under 35 U.S.C. § 101. MPEP § 2106(I). The examiner researches whether each claim of the invention is directed toward one or more of the four patent-eligible subject matter categories of the statute. *Id.* "If the claimed invention is clearly not within one of the four categories, it is not patent eligible." *Id.*

The second step is to analyze whether the claim wholly embraces "a judicially recognized exception, which includes laws of nature, physical phenomena, and abstract ideas," or whether "it is a particular practical application of a judicial exception." MPEP § 2106(II). "The Supreme Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'" *Id.*, citing *Diamond v. Chakrabarty,* 447 U.S. at 309. "While abstract ideas, physical phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, physical phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of 35 U.S.C. 101, the claim must be considered as a whole to determine whether it is for a particular application of an abstract idea, physical

phenomena, or law of nature, and not for the abstract idea, physical phenomenon, or law of nature itself." *Id.*, citing *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

Given that Steps 1 and 2 *supra* are mandatory threshold steps for any examiner to evaluate subject matter eligibility under 35 U.S.C. § 101, under the requirement that the clear and convincing standard must be used to invalidate a claim for ineligible subject matter, a challenger would need to show either that the examiner failed to consider subject matter eligibility or that no reasonable examiner would have allowed a claim that was subject matter ineligible. This is a very high bar.

2. Utility

The starting point for a practical utility analysis is *Brenner v. Manson*, 383 U.S. 519 (1966)[1] Here, the Supreme Court held that, "arguments for and against the patentability of a process which either has no known use or is useful only in the sense that it may be an object of scientific research would apply equally to the patenting of the product produced by the process." *Id.* at 533. Further, the Court stated that a "patent system must be related to the world of commerce rather than to the realm of philosophy." *Id.* at 536.

The C.C.P.A. court held in *In re Chilowsky*, 229 F.2d 457, 462 (C.C.P.A. 1956):

> [*I*]*n the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required. On the other hand, if the alleged operation seems clearly to conflict with a recognized scientific principle as, for*

[1] *See also Cross v. Tizuka,* 753 F.2d 1040, 224 USPQ 739, 744 (Fed. Cir. 1985).

> *example, where an applicant purports to have discovered a machine producing perpetual motion, the presumption of inoperativeness is so strong that very clear evidence is required to overcome it. A third type of case . . .* [*is an invention*] *of such a nature that it* [*cannot*] *be tested by any known scientific principles. In such a case . . . it is incumbent on the applicant to demonstrate the workability and utility of the device and make clear the principles on which it operates.*

Thus, there are three categories of evidence that may be inherent or required to justify a utility rejection. MPEP § 2107 provides guidelines for examination of applications for compliance with the utility requirement. Determination of utility is also a threshold step under 35 U.S.C. § 101 that must be performed by a USPTO examiner before dealing with issues relating to novelty or adherence to requirements of 35 U.S.C. § 112. Under the requirement that the clear and convincing standard must be used to invalidate a claim for non-utility, a challenger would need to show either that the examiner failed to consider the utility of the invention or that no reasonable examiner would have allowed a claim that was not useful.

3. Novelty

As discussed *supra*, 35 U.S.C. §101 imposes a third requirement that the invention be new. A determination of novelty is based solely on a review of the prior art. Prior art is information that was available to the public before a date of priority afforded to the patent application. The challenger cannot assert lack of novelty unless based on prior art, and hindsight cannot form a basis for lack of novelty. The requirements of a determination of novelty are set forth in 35 U.S.C.§§ 102 and 103. This subject will be discussed at length *infra*.

B. 35 U.S.C. § 112(a) - The Specification

35 U.S.C. § 112(a) states:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.*

Section (a) of the statutes sets forth three requirements for a patent application's specification:

- the written description requirement,
- the enablement requirement, and
- the best mode requirement.

Each of these requirements is distinct from the other. The specification may contain a written description that is not enabling. The disclosure may be enabling without describing the invention. The description of the invention may not include the preferred embodiment.

1. The Written Description Requirement

A non-provisional patent application comprises two sections – a specification and claims. The specification discloses the invention to the public. The claims lay out the scope of protection that an applicant seeks for his invention. Although not quite analogous to a contract, a patent document is a *quid pro quo*. In exchange for disclosure of details of the invention and not maintaining it secret, the applicant receives protection against others making,

using or selling what is defined as his scope of protection. The disclosure is separate from the claims. Neither may exist without the other.

The disclosure of the invention is in the form of a written description. The disclosure must be in writing. An audio or video disclosure in not allowed. The written description teaches the reader what the inventor believes his invention to be. Often, a patent application includes drawings that graphically describe the invention, and the written disclosure refers to the drawings. However, drawings are not required. The function of the written description is to explain the invention to the public. It tells the public what the applicant invented in plain language. The public will not understand what the applicant invented unless the inventor describes it in writing. Often a specification will discuss prior art and will explain how the invention overcomes the prior art. But, it is not necessary for the applicant to teach to that degree.

A claim will be rejected under 35 U.S.C. § 112(a) for failing to comply with the written description requirement if the specification fails to describe the claimed invention. Without a written disclosure of the claimed invention, the claim is invalid. However, the written description does not need to be a manufacturing specification.

2. The Enablement Requirement

Enablement relates to the specification teaching a person having ordinary skill in the art how to make and use the invention. First, the invention must be operational. If an invention process comprising a series of steps cannot function as described, then the method claiming that process is not enabled. If a

manufactured article invention does not work, then the claim reciting that article is not enabled. It is possible for an invention to be described adequately, and yet not be enabled. A famous example would be a novel perpetual motion machine. Many inventors filed patent applications describing and claiming perpetual motion devices. However, these are not patent eligible because perpetual motion of a mechanical device defies the laws of physics. A claim to such a device fails the § 112(a) enablement requirement.

Enablement under § 112 is closely related to utility under § 101. An invention that is not enabled is also not useful. However, the converse is not true. It is possible for an invention to be useful, but not enabled.

Second, if the specification does not teach a person having ordinary skill in the art (PHOSITA) how to make and use the invention, there is no enablement. The Federal Circuit held:

> *When rejecting a claim under the enablement requirement of Section 112, the* [*Patent Office*] *bears an initial burden of setting forth a reasonable explanation as to why it believes the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application, this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement*

In re. Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

Claims must be supported by the written description. When a USPTO examiner rejects a claim under 35 U.S.C. § 112(a) for lack of enablement, that rejection means that the portion of the specification that supports the claim describes an invention that either cannot function as described or that fails to teach the person of ordinary skill how to make and use the invention.

Enablement means that practice of the invention must not require undue experimentation, although reasonable experimentation by a person having ordinary skill in the art is permitted. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d 788 (Fed. Cir. 1985). The governing term is "undue." A detailed manufacturing specification is not required, nor is there an obligation to teach the prior art or to compare the claimed invention with prior art. The enablement requirement is met if the description enables any mode of making and using the claimed invention. *Engel Indus., Inc. v. Lockformer Co.,* 946 F.2d 1528 (Fed. Cir. 1991).

The enablement requirement is satisfied when the applicant describes an embodiment (or example) of the invention that works and that a person of ordinary skill can make or use without undue experimentation. A single enabled embodiment is the only requirement.

3. The Best Mode Requirement

An inventor must disclose at least one claimed embodiment. In most cases, inventors disclose multiple claimed embodiments. However, one of the disclosed embodiments must address the best way of performing the invention as conceived by the inventor at the time the patent application is filed. This embodiment is known as the best mode. Where multiple embodiments are disclosed, if one of them is the best mode, the inventor need not state which embodiment represents the best mode.

C. 35 U.S.C. § 112 - The Claims

35 U.S.C. § 112(b)

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.*

35 U.S.C. § 112(c)

> *A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.*

35 U.S.C. § 112(d)

> ***...*** *a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim independent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.*

Regardless of what is taught in the specification, the claims set forth the metes and bounds of the protection sought by the applicant for his invention. The claims must have support in the written description. A claim must appear as a single sentence beginning with a capital letter and ending in a period. An independent claim is one that stands alone. A dependent claim is one that references another claim set forth previously. A claim is generally divided into three parts: (1) a preamble, (2) a transitional word, or phrase; (3) a body.

In an independent claim, the preamble typically explains to the reader what type of process, machine, manufacture, or composition of matter is covered by the claim. Often, the preamble will set forth the utility for the claimed invention. Examples are: "a method for ..." doing something or "a chemical composition that ..." does something. Then, the preamble may lay out various nouns that will appear in the body of the claim. The first appearance of a noun

should appear with a preceding modifier either "a" or "an." All subsequent appearances of that noun should appear with a preceding modifier either "the" or "said." Failure to follow this convention renders the claim indefinite.

If the claim defines a process, then it will begin with the words: "a process for ...," or "a method for ...." The body of such a claim will set forth a series of steps with auxiliary verbs in active voice ending in 'ing.' Examples are bringing, holding, evaluating, *etc*. If the claim defines a machine, manufacture, or composition of matter, the body of that claim will set forth a series of structural elements that define the invention.

The transitional word or phrase connects the preamble of the claim to the body. Three such words or phrases are used:

- comprising (or comprised of) - This term means 'including' or 'having," and is open-ended. As an example, the phrase, "comprising A, B, and C," means that the claimed invention must include elements A, B, and C, but it may have additional elements.
- consisting (or consisting of) - This term leads to a body that is closed. As an example, the phrase, "consisting of A, B, and C," means that the claimed invention must include A, B, and C and no more.
- consisting essentially of - This is a hybrid term that is closed for the essential elements, but may have additional non-essential elements.

A dependent claim is one that references another claim. Generally, the reference to the base claim appears in the preamble. Examples are, "the method of claim 4" or the "chemical composition of claim 4." A dependent claim

incorporates its base claim by reference therein. Thus, a dependent claim cannot be read alone. It acts as an appendage to its base claim. As an example, if claim 4 recites, "a device comprising A, B, and C," then elements A, B, and C must be present, but it can include more. If claim 5 recites, "the device of claim 4 further comprising D," then claim 5 must be read where A, B, C, and D are present, but it can include more.

D. Rejections Based On Prior Art

1. Anticipation Based On 35 U.S.C. § 102(a)

35 U.S.C. § 102(a):

> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
>
> (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

"35 U.S.C. § 102(a) establishes that a person cannot patent what was already known to others." *Woodland Trust v. Flowertree Nursery Inc.*, 148 F.3d 1368 (Fed Cir. 1998). Section § 102(a) is the first of two statutes that addresses the novelty requirement of 35 U.S.C. § 101. A rejection under § 102(a) may only be based on prior art. The effective filing date of a patent is the date of filing of the earliest application to which priority is claimed. Thus, if the patent issued from a particular patent application, and that application claimed priority to one or

more previously filed patent applications, the filing date of the earliest of those applications represents the effective filing date.

Prior art includes:

- a patent issued earlier than the effective filing date,
- a printed publication available to the public earlier than the effective filing date,
- a process, machine, manufacture, or composition of matter in public use earlier than the effective filing date, or
- a patent application published earlier than the effective filing date.

A claim rejection under 35 U.S.C. § 102(a) will be made if the claim is anticipated by the prior art. As discussed *supra*, the body of a claim consists of one or more elements. Anticipation of a claim under §102(a) is made using a single prior art reference. For there to be anticipation, every element of the claim must be taught in that single prior art reference. If that single prior art reference is silent regarding any element of the claim, a rejection under § 102(a) is inappropriate. "In order to anticipate, a prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Azko N.V. v. United States ITC*, 808 F.2d 1471 (Fed. Cir. 1986).[2]

2. Obviousness Based On 35 U.S.C. § 103

35 U.S.C. § 103:

> *A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.*

[2] *See also Ashland Oil Co v. Delta Resins & Refracs.,Inc.*, 776 F.2d 281 (Fed. Cir. 1985) and *Reading & Bates Constr. Co. v. Baker Energy Res. Corp.*, 748 F.2d 645 (Fed. Cir. 1984).

Obviousness is a legal conclusion. *E.g., Aktiebolaget Karlstads v. United States ITC*, 705 F.2d 1565 (Fed. Cir. 1983). It is a question of law to be determined from the facts. *In re. Geiger,* 815 F.2d 686 (Fed. Cir. 1987); *in re. Blauwe,* 736 F.2d 699 (Fed. Cir. 1984). "Whether an invention would have been obvious in terms of §103 is ultimately a legal judgment, dependent from the factual evidence adduced." *Burlington Indus. Inc. v. Quigg,* 822 F.2d 1581 (Fed. Cir. 1987).

It is difficult to arrive at a determination of obviousness. It must be based upon what a person having ordinary skill in the art would have known as prior art earlier than the effective filing date and the inferences that he would have made based on that knowledge. Use of hindsight is impermissible. If the prior art does not contain or suggest that knowledge, the challenger would be using the invention as a template for its own reconstruction. Even if the prior art was available to that fictitious person at the time, there must be a showing that such a person would have considered a claim obvious over the prior art. If much time passed between the effective filing date and the allegation of obviousness, significant care must be taken to insure that he who alleges obviousness does not use his current knowledge of the art to allege obviousness.

Like all legal conclusions, a determination of obviousness is reached after answers to a series of fact questions. *Graham v. John Deere Co. of Kansas City,* 383 U.S. 1, 17 (1966). "Under s 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved."

Because a person having ordinary skill in the art is aware of the prior art, he can combine prior art references to allege obviousness. All patented inventions consist of a combination of old elements. It is not existence of the old elements themselves in a claimed invention that renders the claim obvious, but rather the uniqueness of how they are combined. For example, persons skilled in the art might be familiar with a gear, a cam, or a shaft. Merely because an invention uses gears, cams, and shafts does not make the invention obvious. In other words, if a claim recites a process or other statutory invention comprising elements A and B, it would be improper to combine a reference comprising A with a reference comprising B without further motivation to make that combination. First, it must be possible to combine the references. If A and B cannot be combined, then their combination cannot render the claimed invention obvious. If either one of the references is not enabled for the A element or the B element, then their combination is unwarranted. A person having ordinary skill would not have combined them to make or use the claimed invention. Second, assuming that references can be combined, their combination must produce a process or other statutory item having all of the elements in the claim. The combination may not be silent regarding any element in the claim. Further, the combined elements must function together to accomplish the claimed invention when considered as a whole.

"[S]eeking to resolve the obviousness question with more uniformity and consistency, the Federal Circuit has employed a “teaching, suggestion, or motivation” (TSM) test, under which a patent claim is only proved obvious if the

prior art, the problem's nature, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings." *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 399 (2007). "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art." *Id.* at 401. Further, "[t]o determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art." *Id.*

a. Secondary Consideration – Commercial Success

Commercial success attributable to the merits of the claimed invention is powerful and persuasive evidence of nonobviousness. Commercial success must be considered before a conclusion on obviousness is reached. *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983). "It is entirely proper, nevertheless, in evaluating nonobviousness, for a court to take into account advantages directly flowing from the invention patented. After all, those advantages are the foundation of that "commercial success" which may be evidence of nonobviousness." *Preemption Devices, Inc. v. Minnesota Min. & Mfg. Co.,* 732 F.2d 903 (Fed. Cir. 1984). Evidence of commercial success even

occurring abroad is relevant (if attributable to the merits of the claimed invention), and it is improper for a court to reject it. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.,* 730 F.2d 1452, 1461 (Fed. Cir. 1984).

"Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims." MPEP § 716.03(a)(I) citing *In re Tiffin,* 448 F.2d 791 (C.C.P.A. 1971). "In order to be commensurate in scope with the claims, the commercial success must be due to claimed features, and not due to unclaimed features." *Id.* citing *Joy Technologies Inc. v. Manbeck,* 751 F. Supp. 225, 229, (D.D.C. 1990), *aff'd*, 959 F.2d 226, 228 (Fed. Cir. 1992).

"If a particular range is claimed, applicant does not need to show commercial success at every point in the range, ... and where substantial commercial success is achieved at an apparently typical point within those ranges, and ... operation throughout the claimed ranges approximates that at the particular points involved in the commercial operation, we think the evidence as to commercial success is persuasive." MPEP § 716.03(a)(II) citing *In re. Hollingsworth,* 253 F.2d 238, 240 (C.C.P.A. 1958). See also *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.,* 851 F.2d 1387 (Fed. Cir. 1988).

VI. THE PERSON HAVING ORDINARY SKILL IN THE ART

The person having ordinary skill in the art (hereinafter, the "person of ordinary skill") is key to the §103 statute. It is essential that the nature of the person of ordinary skill be ascertained when deciding whether a claim is obvious. An incorrect determination as to level of skill, or an incorrect finding, may constitute reversible error if it influences the ultimate conclusion on obviousness.

Custom Accessories, Inc. v. Jeffrey-Allen Indus., Inc., 807 F.2d 955 (Fed. Cir. 1986).[3] Care must be taken not to select a person of extraordinary skill. We are presented here with three questions:

1. Who is this person?
2. What is ordinary skill?
3. What does this person of ordinary skill know?

The person of ordinary skill is a hypothetical individual. He is a legal fiction very much like the reasonable person. He is not a genius in the art. Also, he is not an inventor. He is definitely not the inventor of the claimed invention, because the claims are not to be evaluated through the eyes of the inventor. However, he is not an automaton. According to § 112, he is the person who is able to make and use the claimed invention at the earliest filing date without undue experimentation. He is a technician capable of modest experimentation

The level of ordinary skill depends upon the art itself. In some cases, the art is so complex that it would require a researcher with a Ph.D. or a medical degree. In other cases, the art is not complex at all, and would require a competent carpenter to fabricate the claimed invention.

However, this fictitious person of ordinary skill not only has the skill necessary for him to make and use the invention without hindsight, but he also has knowledge of the entire prior art repository in his art and the analogous art. Probative factors are his educational background, his history of employment, the types of problems encountered in the art, the rapidity in which innovations are made, and the sophistication of the technology.

[3] *See also Kloster Speedsteel AB v. Crucible, Inc.,* 793 F.2d 1565 (Fed. Cir. 1986).

A. Nature of the Art

In Paragraph 28 on Page 13 of the Amiji Report, the author states, "I understand that Trutek's products are considered cosmetics given that they did not go through the Federal Drug Administration drug approval process." To that end, he presents as a reference the entire Handbook of Cosmetic Science and Technology as an exhibit stating that it is a leading textbook that discusses the various excipients that are disclosed in the '802 Patent.

In Paragraph 68 on Page 28 of the Amiji Report, the author states:

> *I came to the conclusion that the characteristics of a person of ordinary skill in the art of the '802 Patent would be someone who had at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team—including a chemical engineer, microbiologist, or polymer chemist—and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, e.g., to solve a given problem.*

First, cosmetic formulation and pharmaceutical formulation are two different fields of science. The prior patents and publications in these two scientific areas are different between these two fields. Relating to the '802 Patent, what is common to these two arts is the ability to formulate a product.

B. The Level of Ordinary Skill

It is my opinion that Amiji's definition in Paragraph 28 is for a person of extraordinary skill in the art. As argued *supra*, the person of ordinary skill is not one who would be able to invent the '802 claimed inventions from scratch. He merely needs to make and use it. The specification of the '802 Patent presents ten formulations having similar ingredients, each of which satisfies the claim

limitations. The person of ordinary skill needs to be a person who typically prepares formulations of this type. The educational background cited by Amiji exceeds that of the person of ordinary skill. This person does not need to possess an M.S. degree in chemical engineering or pharmaceutical sciences. The inventor, Ashok Wahi, has a degree in mechanical engineering.

In my opinion, the minimum requirement for a person of ordinary skill is that he should have adequate experience in making chemical formulations. This person does not need an advanced degree. Even an undergraduate degree is unnecessary. This individual can be a chemical laboratory technician who has several years experience in making chemical formulations of the type discussed in the patent specification. At least, he must have taken undergraduate courses in organic and polymer chemistry, as well as courses in physics and biology. He must understand the concepts of static electricity as well as electrostatic attraction and repulsion. He must know what is a cationic agent and be able to identify ingredients that fit this category. He must know what is a biocidic agent and be able to identify ingredients that fit this category. He must understand the concepts of adhesion and cohesion. Finally, he must understand the various categories of harmful airborne particles, such as bacteria, viruses, pollen, and other airborne allergens. This does not require an advanced degree.

C. Knowledge of the Person of Ordinary Skill

The person of ordinary skill is familiar with all art prior to the effective filing date of the '802 Patent. He would know how to create all of the formulations in the specification of the '802 Patent. However, for the method of claim 1 of the

'802 Patent or the formulation of claim 2 of the '802 Patent to be obvious to this person of ordinary skill, based upon his level of skill and knowledge in the art of chemical or pharmaceutical formulation, he would have been required to conclude that a formulation applied to a person's nostrils would be able to inhibit inhalation of and subsequent infection from harmful particles *via* creation of an electrostatic field. He would have to understand how to manipulate adhesion and cohesion of the formulation so as to hold these harmful particles in place until they could be inactivated. Multiple prior art references at the time would have needed to teach or suggest such a method and formulation such that the person of ordinary skill would have been motivated to combine the references to make the claimed invention. The type of formulation recited in claims 1 and 2 should be so familiar to him that it would have been obvious for him to create it. However, in that case, prior to conceiving such a formulation, he could not be permitted to see the '802 Patent. The '802 Patent is not prior art.

VII. U.S. PATENT NO. 8,163,802 (THE '802 PATENT)

The '802 Patent is shown as Exhibit 1 of the Amiji Report. The '802 Patent discloses and claims a method and formulations, which applied to a person's nostrils, electrostatically captures harmful particles that the person would otherwise inhale, holds those particles in place, and renders them harmless. The process can be thought of as CATCH, HOLD, and KILL.

The patent consists of an abstract, a specification, and twenty-three claims.

A. The Abstract

The abstract discloses:

> A product to reduce and method of reducing the risk of inhalation of harmful substances by applying a formulation composition to a substrate or the skin in close proximity of one or more nostrils. This formulation, when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact the substrate or skin less harmful.

B. The Specification

In the Background of the Invention section of the specification, the Applicant defines the problem. Normally, a person inhales a huge amount of airborne particulate matter through his nose with every breath. Probably, most of the inhaled particles are harmless. However, inhalation of certain particles can trigger allergic reactions or can cause infection and illness. The section further describes that some people use face masks to filter out these irritants. However, these are inadequate and inefficient for their purpose. The section proceeds to

describe compositions previously patented by the same inventor[1] that create an electrostatic field around the nose that helps to filter out charged harmful particles. These compositions act merely to filter some, but not all harmful particles so as to prevent them from reaching the nose. Although this material offers some protection against particles that are inhaled passively, they cannot completely deal with particles that have their own internal means for overcoming the electrostatic forces. The particles are not captured and they are not held in place. These compositions are merely filters.

The objects of the invention listed in the specification are:

1. to provide a composition that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release with method and compositions capable of capturing particulates and microorganisms;

2. to have the capability to hold it for a duration from being dislodged in to the air stream again;

3. to provide a composition that can be applied near the vicinity of the source of release or to the area around the exterior of and/or slightly inside the edge of the nostril that will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition;

4. to provide a composition that can be applied to a filter substrate for improving the substrates ability to trap and hold particulates and microorganisms and to simultaneously inactivate, kill, or render harmless the microorganisms so trapped. Such filter substrate could be placed in the close proximity of the skin near the path of inhalation, near the source of release of such particulates while the inhaler is at a distance or both; and

5. to provide a method of prophylactically preventing or of substantially reducing the risk of infection by an infectious agent without the utilization of ingested antiviral and/or antibacterial agents.

[1] The Section describes U.S. Patent 6,844,005 issued to Wahi, also the inventor listed on the '802 Patent.

Object #1 describes CATCHING. Object #2 describes HOLDING. Object #3 describes KILLING. Object #4 describes CATCHING, HOLDING, and KILLING.

The specification then lists the bacterial and viral diseases that can be caused through inhalation. It next lists the environmental particulate diseases that can be caused through inhalation. The specification lists the ingredients that make up the various formulations that meet the criteria listed in the above five objectives. Among the ingredients listed are (1) a surfactant, (2) a thickener, and (3) a binder. A surfactant is a substance that lowers the surface tension between a liquid and another material. A thickener is a substance that increases the viscosity of a liquid without affecting its other properties. A binder (or binding agent) is a material or substance that holds or draws other materials together to form a cohesive whole mechanically, chemically, by adhesion or cohesion.

Then, there are ten actual formulations listed in tables. In those listed formulations, concentrations of many of the ingredients are listed in ranges. However, all of the formulations listed in the tables will function to achieve the five objectives and will act as recited in the claims. A person of ordinary skill should have no difficulty creating the formulations listed in the tables. That person is a skilled formulator. He should be able to adjust the concentrations of the various ingredients to achieve the ideal composition that meets the criteria expressed in the five objectives *supra*.

C. <u>The Claims</u>

The claims at issue in this lawsuit are claims 1, 2, 6, and 7. The Amiji Report alleges that claims 1, 2, 6, and 7 are invalid (1) for being directed to ineligible subject matter under 35 U.S.C. § 101; (2) for lack of credible utility; (3) for lack of enablement; (4) for lack of adequate written description; (5) for being anticipated by prior art; and (6) for being obvious in view of the prior art.

1. Claim 1

1 A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

a) electrostatically attracting the particulate matter to the thin film;

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

Claim 1 is an independent claim. It is a stand-alone method claim. The preamble lists the purpose or use for the method. However, the words of the preamble are closely related to the body of the claim. The object nouns of the claim are first revealed in the preamble:

- harmful particulate matter,
- an individual,
- a formulation,
- skin or tissue (of nasal passages of the individual), and
- a thin film.

Thus, the preamble becomes an integral part of the claim because without it, the claim would be indefinite. Thus, the process uses a formulation that is applied to the skin or tissue of the nasal passages of an individual in a thin film to accomplish the process denoted by the steps recited in the body of the claim.

Essential to the claim is the formation of a thin film on the skin or tissue of the individual's nasal passages.

The method (process) claim has three steps:

a) CATCHING - *i.e.,* electrostatically attracting the particulate matter to the thin film;

b) HOLDING - *i.e.,* holding the particulate matter in place; AND

c) KILLING - *i.e.,* inactivating the particulate matter.

Step (a) requires that the formulation should contain an ingredient that creates and electrostatic field, the charge of which would attract harmful particles that have an opposite charge.

The claim further recites how steps (b) and (c) are to be accomplished.

STEP (b) - recites holding the particulate matter in place by ***adjusting the adhesion*** of the thin film to permit said thin film to stick to the skin or tissue and by ***adjusting the cohesion*** of the formulation to provide adequate impermeability to the thin film. This is performed by ***adding ingredients to the formulation***, *e.g.,* (1) a surfactant, (2) a thickener, and (3) a binder, among others. The formulation needs to adhere to the skin or tissue of the nasal passages in a thin film. The thin film also needs to be sticky and viscous so as to both adhere to the skin or tissue and to hold the particulate matter in place. Given the disclosure in the specification, a person of ordinary skill as a formulator would know which ingredients to include in the formulation to adjust the adhesive and cohesive properties of the formulation. This is done all by chemical and pharmaceutical formulators all the time. Getting the concentrations correct to

produce an ideal formulation would not consume undue experimentation given that the ingredient ranges of the example formulations are provided in the tables.

STEP (c) - recites inactivating the particulate matter by ***adding at least one ingredient*** that would render said particulate matter harmless. Biocides are among the class of ingredients that would accomplish this step. However, the ingredient concentrations are important to distinguish between preservative action and biocidic action. Once again, the concentration ranges given in the ten example formulations work as described in the specification.

2. Claim 2

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:

a) electrostatically attracts the particulate matter to the thin film;

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

Claim 2 is an independent claim. It is a stand-alone formulation claim. A formulation claim is for both a composition of matter and a manufactured article. The preamble lists the use for the formulation. However, the words of the preamble are closely related to the body of the claim. The objects of the claim that are first listed in the preamble:

- a formulation,
- harmful particulate matter,
- an individual,
- skin or tissue (of nasal passages of the individual), and

- a thin film.

Thus, the preamble becomes an integral part of the claim because without it, the claim would be indefinite. Thus, the claimed formulation is applied to the skin or tissue of the nasal passages of an individual in a thin film. The formation of a thin film on the nasal passages of the individual is a mandatory aspect of the claim.

The transitional word or phrase is 'comprising,' thus providing for elements or ingredients that must be present in the formulation, but may include additional elements or ingredients. Further, there may exist additional limitations, which may be recited in dependent claims.

Although appearing in the same paragraph as the preamble, but following the transitional word, 'comprising,' are:

- at least one cationic agent, and
- at least one biocidic agent.

A cationic agent is a substance that produces a positive electrostatic charge. The ingredients of the formulation must include one cationic agent, but more of them may be present.

A biocidic agent (or biocide) is a substance that destroys or inhibits the growth or activity in living organisms. The ingredients of the formulation must include one biocidic agent, but more of them may be present.

Although the two above limitations appear in the same paragraph as the preamble, the body of the claim begins immediately following the word, 'comprising.'

Once again the formulation contains ingredients that do three things: (a) CATCH, (b) HOLD, and (c) KILL. The ingredients, when joined together, must do all three things:

(a) CATCH - *i.e.*, the formulation electrostatically attracts the particulate matter to the thin film;

(b) HOLD - *i.e.*, holds the particulate matter in place; AND

(c) KILL - inactivates the particulate matter and renders said particulate matter harmless.

The cationic agent is the ingredient in the formulation that CATCHES the harmful particulate matter by electrostatically attracting it to the thin film. (*I.e,* ELEMENT (a).) It is well known that almost all harmful airborne particles are negatively charged. These include dust particles, mites, pollen, and microbes. Thus, because the cationic agent produces a positive electrostatic charge in the thin film on the surface of the individual's nasal passages, harmful particles floating in the vicinity of the individual's nose will be attracted to the thin film. They will be CAUGHT.

ELEMENT (b) - recites that the formulation holds the particulate matter in place by ***adjusting the adhesion*** of the thin film to permit said thin film to stick to the skin or tissue and by ***adjusting the cohesion*** of the formulation to provide adequate impermeability of the thin film. This is done by ***adding ingredients to the formulation***, *e.g.*, (1) a surfactant, (2) a thickener, and (3) a binder, among others. The formulation needs to adhere to the skin or tissue of the nasal passages in a thin film. The thin film also needs to be sticky and viscous so as to both adhere to the skin or tissue and to hold the particulate matter in place.

Given the disclosure in the specification, a person of ordinary skill as a formulator would know which ingredients to include in the formulation to adjust the adhesive and cohesive properties of the formulation. This is done by chemical and pharmaceutical formulators all the time. Getting the concentrations correct to produce an ideal formulation would not consume undue experimentation given that the ingredient ranges of the example formulations are provided in the tables.

ELEMENT (c) - recites that the formulation inactivates the particulate matter, and renders it harmless. This task is performed by the ***at least one biocidic agent***. It is important to note that biocides are also used as preservatives in many products currently on the market. The purpose of a preservative is to prevent decay and to extend the lifetime of these products. The ability of the formulation of the '802 Patent to inactivate virtually all harmful particles coming in contact with the thin film depends upon the concentration of the at least one biocidic agent (to KILL) as well as the concentrations of the other ingredients (to CATCH and HOLD) the harmful particles in place.

The '802 Patent was issued on April 24, 2012. Prior to 2012, during the pendency of the patent application, Plaintiff Trutek Corp. ("Trutek"), formulated a product initially named NasalGuard® MAPB™,[2] which was formulated based upon the example formulations shown in the specification of the '802 Patent. The acronym MAPB™ was never used on any product manufactured, licensed, or sold by Trutek. All of the products sold by Trutek between 2012 and the current date are based upon the specification and claims of the '802 Patent. The technology for these subsequent products is still referred to internally by Trutek

[2] MAPB™ is an acronym for **M**ulti-**A**cting **P**article **B**locker.

as MAPB™. Trutek's products all use the term NasalGuard® as a part of their brand name.[3]

Prior to the '802 Patent being issued, Trutek submitted samples of MAPB™ gel to Max Neeman International[4] to ascertain their efficacy as a preventive treatment for the common cold and influenza. The study was conducted over 8 weeks on 600 healthy subjects, divided evenly between a group that used the MAPB™ gel and a control group. The study concluded that "MAPB nasal application gel was considered as an efficacious and safe gel in prevention of common cold and/or flu in healthy subjects." A portion of the study report is attached hereto as Exhibit D.

3. Claims 6 and 7

Claims 6 and 7 are dependent claims that depend from claim 2. Thus, claim 6 and claim 7 must be read as though they are a part of claim 2. All of the limitations of claim 2 are incorporated therein. Claim 6 states that the at least one cationic agent of the formulation of claim 2 is Benzalkonium Chloride. Claim 7 states that the at least one biocidic agent of the formulation of claim 2 is Benzalkonium Chloride. Benzalkonium Chloride is a known cationic agent and a known biocidic agent. It is used as an ingredient in the '802 Patent formulations, and functions effectively in a concentration of 0.25% to 1% by weight.

[3] The brand NasalGuard® is a registered trademark in several countries as well as in the United States.
[4] Max Neeman Medical International, Ltd. is a research institute in New Delhi, India. It was acquired by JSS Medical Research, Inc. in 2015.

VIII. REBUTTAL TO BLUEWILLOW'S ALLEGATIONS OF INVALIDITY

A. The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101.

Paragraph 202 on page 95 of the Amiji report states:

> *The '802 Patent is directed to the effects of a law of nature or a natural phenomena, namely the principle that like charges repel each other, while unlike charges attract, e.g., a positive charge attracts a negative charge. While the Challenged Claims of the '802 patent recite additional elements, each of those additional claim elements are either conventional steps that are well known to a POSA or depend on the very same law of nature or natural phenomena. Thus, in my opinion, the '802 Patent claims do not recite any inventive concept that would transform the law of nature into a patent eligible invention.*[1]

The author continues with an analysis in Paragraphs 203 - 211 for four pages to allege that the claims are directed to laws of nature and natural phenomena, and that this represents ineligible subject matter. He points out that electrostatic attraction is a natural phenomenon. Amiji Pg. 95, ¶ 203. He alleges that Claims 1, 2, 6, and 7 are directed to electrostatic attraction, which is a natural phenomenon. *Id.* He alleges that attracting oppositely charged particles, such as airborne contaminants is similarly a natural phenomenon. *Id.* at ¶ 204. He then states, "With respect to the second step of the § 101 test, it is also my opinion that each of the additional elements of the Challenged Claims recite nothing more than well-understood, routine and conventional activity or are directed to the very same law of nature or natural phenomena." *Id.* at ¶ 205. Further, he indicates that there is no inventive step because a person of ordinary

[1] POSA is Amiji's acronym for Person of Skill in the Art. This person is referred to in my expert report as a "Person Having Ordinary Skill In The Art," "PHOSITA," and "person of ordinary skill."

skill would know how to direct his activities toward harnessing this natural phenomenon.

Patentable subject matter under 35 U.S.C. § 101 includes new and useful inventions that claim processes, machines, manufactured articles, compositions of matter, and any new or useful improvements thereof. There are two issues relevant to § 101 – utility and subject matter eligibility. This section is devoted to subject matter eligibility. The issue of utility will be dealt with in Section VIII-B *infra*.

The first step in a § 101 analysis is to determine whether the claimed invention is one of the types of inventions patentable. Claim 1 of the '802 Patent recites a method, which is otherwise known as a process. It is a series of steps required to accomplish a task. Claims 2, 6, and 7 recite a formulation, which is both a manufactured article and a composition of matter. Thus, claims 1 and 2 recite inventions that are covered under § 101.

The second step is to determine whether the invention's claims wholly embrace non-man-made judicial exceptions to patentability, *e.g.,* laws of nature, physical phenomena, and abstract ideas, or whether "it is a particular practical application of a judicial exception." *Diamond v. Chakrabarty,* 447 U.S. 303, 309 (1980). *See also* MPEP § 2106(II). "While abstract ideas, physical phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, physical phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of 35 U.S.C. 101, the claim must be considered as a whole to

determine whether it is for a particular application of an abstract idea, physical phenomena, or law of nature, and not for the abstract idea, physical phenomenon, or law of nature itself." *Id.*, citing *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

Here, the '802 Patent does not claim electrostatic attraction or repulsion. It does not claim that positive and negative particles are attracted to each other. Nor does it claim the natural phenomena of adhesion, cohesion, or biocidic action. Instead, claim 1 recites a process that utilizes electrostatic attraction, adhesion, cohesion, and biocidic action. And, claims 2, 6, and 7 claim a manufactured article and composition of matter that utilize electrostatic attraction, adhesion, cohesion, and biocidic action.

As in claim 2, inclusion of a cationic agent ingredient in a formulation that causes negatively charged particles to be attracted to the formulation is not the equivalent of claiming electrostatic attraction itself. The claim does not wholly embrace the natural phenomenon of electrostatic attraction. It is instead a formulation that contains an ingredient that produces a positive electrostatic charge in sufficient concentration to attract negatively charged airborne particles. It is a practical invention that utilizes a natural phenomenon. By analogy, a claimed invention reciting a nuclear reactor that utilizes Einstein's law $E=mc^2$ does not wholly embrace or claim the law itself.

In Paragraphs 206 - 211 of the Amiji Report, the author states that the claims recite elements already known to persons of ordinary skill and allegations that the patent fails to adequately describe the invention.

In my opinion, Amiji misinterprets 35 U.S.C. § 101 and is generally unaware of the law and the steps that USPTO patent examiners take to examine for subject matter eligibility.

Moreover, USPTO Patent Examiner Raymond Henley III examined the application that issued as the '802 Patent. It is the first task of a USPTO patent examiner to determine subject matter eligibility under § 101. It is a threshold task performed by all patent examiners. This is codified in MPEP § 2106. Under a clear and convincing evidentiary standard, in order to prove invalidity based on ineligible subject matter, the challenger would need to show either that Examiner Henley did not seek to determine whether the claims were directed to eligible subject matter or that no reasonable examiner would have allowed the application to issue as a patent based on the conclusions put forth by Amiji.

In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101.

B. <u>The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of credible utility</u>.

In the Amiji Report, the author states the following:

> *As an object of the claimed invention, the '802 Patent states that "to accomplish the present invention, a formulation having at least one polyquaternary ammonium compound is prepared, such compounds, alone or together capable of creating an electrostatic field on and around a surface to which it is applied." '802 patent at 4:39-43.*

Pg. 99. ¶ 213.

> *A person skilled in the art reading the '802 patent specification, however, would understand that while the '802 patent does provide a laundry list of possible formulations, it does not include any data or test results for any of the formulations described, demonstrating to a person skilled in the art that there is a substantial likelihood that the claimed invention will work by "electrostatically attracting" particulate matter to a thin film applied to the nasal passages and holding the particulate matter in place through adhesion to the thin film in order to electrostatically inhibit such harmful particulate matter from infecting an individual. Nor does the '802 patent even provide any discussion or suggestion of what types of tests or procedures could be employed by a person skilled in the art to determine whether such formulations would work as described and claimed. Finally, the '802 patent also does not include any explanation or suggestion that the claimed invention is likely to work based on any similarities or analogies to other compositions or formulations that are known to work in a similar manner.*

Id. at ¶ 214.

Once again, Amiji misunderstands the law. 35 U.S.C. § 101 states that a patented invention must be useful. This is the § 101 utility requirement. There are two aspects relevant to a utility determination. The first is satisfied when a patentee asserts a practical use for his invention. Here, the preambles of claim 1 and 2 teach the practical use of "inhibiting harmful particulate matter from infecting an individual through nasal inhalation." Claims 6 and 7 incorporate the use recited in claim 2 by reference. MPEP § 2107 instructs patent examiners as follows:

> *Practical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be "useful." Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is "useful" for a particular reason.*

Thus, if the inventor asserts that his invention is useful, patent examiners are instructed to rely on that assertion. However, "[A]n application must show

that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *In re Fisher,* 421 F.3d 1365, 1371 (Fed. Cir. 2005).

"Rejections under 35 U.S.C. 101 based on a lack of credible utility have been sustained by federal courts when, for example, the applicant failed to disclose any utility for the invention or asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or was wholly inconsistent with contemporary knowledge in the art." *In re Gazave,* 379 F.2d 973, 978 (C.C.P.A. 1967). Who would say that, "inhibiting harmful particulate matter from infecting an individual through nasal inhalation" violates any law of nature or defies contemporary knowledge.

The Amiji Report's allegation of lack of credible utility spans from Paragraph 212 on page 99 until Paragraph 217 on page 101. Paragraphs 215-217 deal mainly with novelty and enablement. They discuss that uses of cationic agents, Benzalkonium Chloride, quaternary ammonium compounds, are well known by persons of ordinary skill. Claims 1, 2, 6, and 7 describe a use that is beneficial to the public, and the specification and claims provide information that a person of ordinary skill would employ to make and use the formulations described therein without undue experimentation.

Both subject matter eligibility and utility are inquiries that need to be made regarding 35 U.S.C. § 101. Inquiries into novelty are best made relative to

statutes 35 U.S.C. §§ 102 and 103. The inquiry into utility of the claims of the '802 Patent is a threshold issue that a patent examiner must perform. This is codified in MPEP § 2107. Under a clear and convincing evidentiary standard in order to prove invalidity based lack of credible utility, the challenger would need to show either that Examiner Henley did not seek to determine whether the claims had credible utility or that no reasonable examiner would have allowed the application to issue as a patent based on the conclusions put forth by Amiji.

In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of credible utility under 35 U.S.C. § 101.

C. The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of enablement.

Utility and enablement are two separate but related properties of a claim. The enablement requirement stems from 35 U.S.C. § 112(a):

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Enablement means that practice of the invention must not require undue experimentation, although reasonable experimentation by a person having ordinary skill in the art is permitted. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d 788 (Fed. Cir. 1985). The enablement requirement is met if the description enables any mode of making and using the claimed invention. *Engel Indus., Inc. v. Lockformer Co.,* 946 F.2d 1528 (Fed. Cir. 1991).

For a claim to be enabled, it must relate to matters taught in the specification. The specification of a patent often teaches several ways that the inventor conceived to implement the invention. Each way to implement the invention is called an embodiment. It is sometimes referred to as an example. The inventor is only required to describe a single embodiment. In that case, the single embodiment must be what the inventor conceives at the time as being the best mode of operation. However, when multiple embodiments are disclosed, only one of them is the best mode, and the inventor is not required to disclose which embodiment is the best mode.

In the '802 Patent, ten different embodiments are taught in the specification. Each one is a formulation that has been shown to work. They all read on the claims of the '802 Patent, and particularly on claims 1, 2, 6, and 7. In the Amiji report, the author complains that the formulations do not have specific percentage concentrations, but appear in ranges. He alleges that this would prevent one from reproducing the various formulations. However, it is known that the embodiments listed in the written description do not need to describe a manufacturing specification. The description does not need to teach a person of ordinary skill something with which he is already familiar. Though the formulations' ingredients are listed by concentration ranges, all of the listed concentrations will create formulations that are fit for their intended purposes. A formulator, who is a person of ordinary skill, would be able to make each of the formulations without undue experimentation. The NasalGuard® product formulations that use the MAPB™ technology derive from the ten embodiments

described in the specification. The use of the formulations in preventing infections from harmful microbial particles (*e.g.,* viruses) is described in the specification. That the product is efficacious against the common cold and influenza is demonstrated by the clinical study of Exhibit D. A person of ordinary skill could easily use the claimed formulation for its intended purpose once he has fabricated it.

In the Amiji Report, respectively, the author complains that claims 1 and 2 are broad. Independent claims are supposed to be broad. An inventor is entitled to as much of his invention that is not taught by the prior art.

The '802 Patent issued after allowance of U.S. Patent Application Serial No. 12/467,271. In a first office action on the merits of the '271 Application on August 25, 2011, Examiner Raymond Henley III issued a non-final rejection of claims 1-23 under 35 U.S.C. § 112, First Paragraph (now § 112(a)) based on lack of enablement. The 08/25/2011 office action is attached hereto as Exhibit E.

The enablement problem seen by Examiner Henley had to do with the term "preventing," as used in independent claims 1, 2, and 8. Claims 1 and 2, as originally submitted with the filing of the '271 Application are shown in Exhibit F attached hereto. The term "preventing" appears in the first lines of both claims 1 and 2. In the Office Action, the Examiner stated:

> *Here, the objective truth of the statement that an infection, which is taken to mean the introduction of an infections element through the outside of a given host and into the system of such host. ... may be prevented, ... i.e., a material is ever kept from introduction into the system of a host, is doubted because the present claims merely recite a pharmaceutical composition while an effective prevention against the introduction of all infectious material into a host, especially where such material does not cause any pathology,*

> *would require that the exterior system of the host be completely blocked so as to preclude any infections material passing through such system and arriving within the system of the host.*
>
> *In reading the specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not, may be* ***inhibited*** [2] *rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host.*

The Examiner explained how to overcome the rejection:

> *In order to overcome the rejection set forth infra, it is suggested that Applicant consider amending claims 1, 2, and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting." While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.*

As a result of this non-final rejection, the Applicant amended claims 1, 2, and 8 by following the suggestion of the examiner and substituting "inhibiting' for "preventing" on the first line of each of the three independent claims. That was the only change made to the claims. Amended claims 1 and 2 are identical to claims 1 and 2 of the '802 Patent. On March 12, 2012, without further comment, Examiner Henley issued a Notice of Allowance for claims 1-23 of the '271 Application.

During prosecution, Examiner Henley explored the issue of enablement under 35 U.S.C. § 112(a). Other than requiring a minor amendment, the fact finder determined that the disclosure in the specification enabled the claims. At the time, Raymond Henley III was a senior examiner.

[2] Emphasis supplied.

Under the clear and convincing evidentiary standard, the challenger would need to show that no reasonable examiner would have rejected the claims for lack of enablement, and to provide clear and convincing evidence that Examiner Henley was incorrect in his decision to allow the claims.

In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of enablement.

D. <u>The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of adequate written description</u>.

The Amiji Report states as follows:

> *It is my opinion that the '802 patent specification does not reasonably convey to a person skilled in the art that the inventor was in possession of any formulation or composition that would operate in the manner claimed in the '802 patent as of the filing date of the application.*
>
> *Amiji,* Pg. 108, ¶ 236.
>
> *While the '802 patent specification describes numerous formulations and different ranges of components that are purportedly within the scope of the claimed invention, the specification provides no data or testing of any kind demonstrating to a person of skilled in the art that the mere fact of applying a thin film having a positive charge will operate to "electrostatically attract" negatively charged particulate matter, adhering such particulate matter to the thin film, thereby inhibiting the particulate matter from infecting an individual. Nor does the '802 patent specification provide any indication to a person skilled in the art that the inventor even tested any of the formulations disclosed in the patent to assess whether they actually operate to electrostatically inhibit harmful particulate matter from infecting an individual through nasal inhalation. In other words, a person skilled in the art reading the '802 patent would understand that the inventor merely had a wish or hope that the claimed invention would operate in the manner described.*
>
> *Amiji,* Pg. 109, ¶ 237.

It is astounding that by saying, "the specification provides no data or testing of any kind demonstrating to a person of skilled in the art that the mere fact of applying a thin film having a positive charge will operate to “electrostatically attract” negatively charged particulate matter, adhering such particulate matter to the thin film, thereby inhibiting the particulate matter from infecting an individual." Amiji fails to recognize basic laws of physics relating to static electricity. Any person who took a course in high school physics in the United States knows that oppositely charged particles attract each other, and similarly charged particles repel each other. A patent specification needs no experimental data to demonstrate this.

There are ten actual formulations listed in tables. In those listed formulations, concentrations of many of the ingredients are listed in ranges. Specific concentrations are not required because all of the formulations listed in the tables will function as recited in the claims. A person of ordinary skill should have no difficulty creating the formulations listed in the tables. That person is a skilled formulator. Amiji complains that the written description provides no data to show that the particulate matter adheres to the thin film. However, among the ingredients listed are (1) a surfactant, (2) a thickener, and (3) a binder. A surfactant is a substance that lowers the surface tension between a liquid and another material. A thickener is a substance that increases the viscosity of a liquid without affecting its other properties. A binder (or binding agent) is a material or substance that holds or draws other materials together to form a cohesive whole mechanically, chemically, by adhesion or cohesion. Thickeners,

binders, and surfactants are well known to persons of ordinary skill. The specific ingredients used are listed in the ten formulations of the specification. In addition, various biocides are listed as ingredients in the ten formulations. A person of ordinary skill would know that biocides in the concentration ranges provided would adequately perform the task of inhibiting the harmful particles from infecting the individual.

A patent specification is not a scientific paper. The written description requirement of 35 U.S.C. § 112(a) is that it must be complete enough as to enable a person of ordinary skill to make and use the invention. It does not need to teach the prior art to those who are unfamiliar with it. It is not necessary to publish results of experiments. The study in Exhibit D proves that the formulations inhibit infection from cold and flu viruses as claimed. The ten formulations work. Thus, as long as a person of ordinary skill **can formulate** the example formulations, **and** as long as he **can use** any of those formulations as prescribed, the written description requirement of § 112(a) is met.

In the office action of Exhibit E, Examiner Henley stated:

> [i]*t is suggested that Applicant consider amending claims 1, 2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification,* ***it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole*** [3]

Thus, the fact finder clearly considered whether the written description requirement of § 112(a) was fulfilled. He evaluated the listed formulations, and stated that the claims find "support when the specification's teachings are taken

[3] Emphasis added.

as a whole." Thus, under a clear and convincing standard, invalidity of the claims for failure to fulfill the written description requirement can be made only if it can be shown that no reasonable examiner would have allowed the claims.

In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of adequate written description.

E. The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wahi '488 alone, or in combination with Rolf.

Wahi '488 refers to U.S. Patent No. 5,468,488 issued to Ashok Wahi on November 21, 1995. A copy of Wahi '488 is attached to the Amiji Report as his Exhibit 5.

1. Validity Analysis Based On Wahi '488 Alone.

Wahi '488 teaches and claims a method for restricting the flow of airborne contaminants into a nasal passage. It involves creating an electrostatic field in an area near a human nasal passage. The electrostatic field may either repel or attract airborne contaminants or both." *Id.* Abstract.

Wahi '488 is closely related to U.S. Patent No. 5,674,481 ("Wahi '481" – attached to the Amiji Report as Exhibit 6) issued to Ashok Wahi on October 7, 1997. The Wahi '481 patent is a continuation patent of and claims priority to Wahi '488. The teachings of the two patents are virtually identical. While Wahi '488 teaches and claims a method, Wahi '481 teaches and claims products that implement the method.

For a claim of an issued patent to become invalid based upon prior art, the prior art must teach or suggest each and every element of that claim. When such a condition arises from reference to a single prior art reference, invalidity is based upon anticipation under 35 U.S.C. § 102(a). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 (Fed. Cir. 1987).

As discussed in Section VII of my report *supra*, independent claim 1 of the '802 Patent recites a method for electrostatically inhibiting harmful particles from infecting an individual by applying a formulation to the individual's nasal passages in a thin film. The three elements (a, b, and c, respectively) of the claim recite CATCHING (electrostatically attracting), HOLDING (holding), and KILLING (inactivating the particulate matter and rendering it harmless).

Independent claim 2 of the '802 Patent recites a formulation product for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation, wherein the formulation is applied to the skin or tissue of the individual's nasal passages in a thin film. The formulation contains, among other ingredients, at least one cationic agent and at least one biocidic agent. The three elements (a, b, and c, respectively) recite that the formulation product CATCHES (electrostatically attracts), HOLDS, and KILLS (inactivates the particulate matter and renders it harmless).

Dependent claims 6 and 7 merely recite a limitation on the claim 2 formulation that the cationic agent and biocidic agent are Benzalkonium Chloride.

The recitation of CATCH, HOLD, and KILL are essential elements all four claims. In order to anticipate these claims, the prior art must teach all of the elements of CATCH, HOLD, and KILL. Further, the claims must teach application of the formulation in a thin film. HOLDING must be accomplished by adjusting the adhesion and cohesion of the formulation. And, relating to claim 2, the formulation must contain at least one cationic agent and at least one biocidic agent.

The objective of the '488 method and the '481 product is merely to restrict the flow of airborne contaminants into an individual's nose by inhalation. The '481 Patent teaches that creation of an electrostatic field near an individual's nasal passages can inhibit (or lessen) the number of airborne contaminants that are inhaled by the individual. Nowhere in either the '488 or '481 Patents is it taught that a product is applied to the skin or tissue of the nasal passages. If the electrostatic field is negatively charged, then negatively charged particles will be repelled by the field, and they will be deflected from the nostrils and not inhaled. On the other hand, it the electrostatic field is positively charged, then negatively charged particles will be attracted to the formulation, *i.e.,* they will be caught and will not be inhaled. Neither the '488 nor the '481 Patent teaches HOLDING or KILLING. Nothing in the patents teaches that the particles will not be dislodged and inhaled after being CAUGHT. Moreover, nothing in the patents teaches that the particles are KILLED (inactivated and rendered harmless). Therefore, Wahi '488 cannot anticipate claim 1, and Wahi '481 cannot anticipate claims 2, 6, or 7.

An allegation of invalidity of claims 1, 2, 6, and 7 under 35 U.S.C. 102(a) cannot stand.

In addition, Examiner Henley considered both Wahi '488 and Wahi '481 during examination of the application that issued as the '802 Patent. Exhibit C (attached hereto) shows the examiner's initials next to items 14 (Wahi '488) and 15 (Wahi '481). Because a clear and convincing showing is required to invalidate a patent, the fact that the examiner considered these two prior art references and allowed the patent application to issue as the '802 Patent should be given great deference.

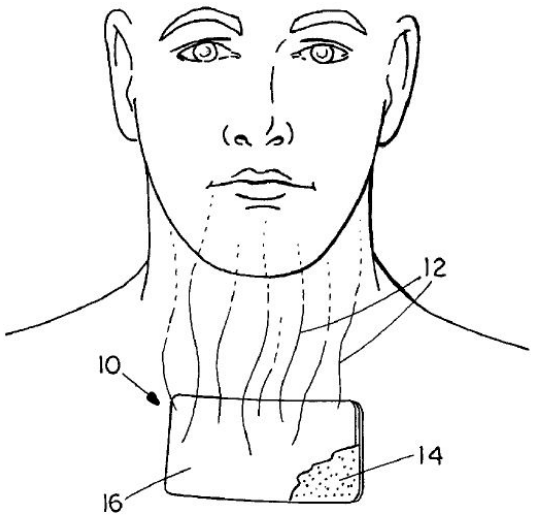
In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wahi '488 alone.

2. Validity Analysis Based On Wahi '488 In Combination With Rolf.

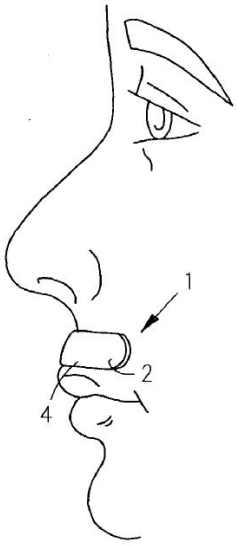
As argued *supra*, for a claim of an issued patent to become invalid based upon prior art, the prior art must teach or suggest each and every element of that claim. 35 U.S.C. § 103 provides that even if a claim is not anticipated under §102, it may still be unpatentable if the differences between the claimed invention and the prior art as a whole would have been obvious before the effective filing date of the claimed invention to a person of ordinary skill. When evaluating a claim for patentability, an examiner may combine two or more prior art references to determine whether the claimed invention would have been obvious to a person of ordinary skill at the time the invention was conceived. *Pre-AIA* 35 U.S.C. § 103(a).

In the Amiji Report, the author alleged that claims 1, 2, 6, and 7 would have been unpatentable over the combination of Wahi '488 with U.S. Patent Application Publication 2004/0071757 A1 (hereinafter, "Rolf") published by the USPTO on April 15, 2004 of U.S. Patent Application No. 10/458,078 submitted by David Rolf. The Rolf Application Publication is attached to the Amiji Report as Exhibit 4.

The Rolf application never issued as a patent. Attached hereto as Exhibit G is USPTO office actions generated during prosecution of Rolf's patent application. In that office action, the examiner rejected all of Rolf's pending claims based on obviousness double patenting, and under statutes 35 U.S.C. §§ 112, 102, and 103. The first of these rejections was based upon a non-statutory, judicially created doctrine often referred to as obviousness double patenting. The claims of Rolf were deemed obvious over the teachings of an earlier patent listing him as an inventor, *viz.,* U.S. Patent No. 6,090,403 ("Block") issued on July 18, 2000. A copy of Block is attached hereto as Exhibit H.



The invention made by Block (shown in the above drawing) is a patch (10) impregnated with a vaporizable decongestant (12), wherein the patch adheres to the skin below the individual's face *via* an adhesive. This invention is similar in action to Vicks® VapoRub® ointment, a well known product that is applied to a person's chest. In both products, vaporizable decongestants evaporate and are inhaled by the individual. "Once vaporized, the aromatic decongestant is available for natural inhalation through the nose or mouth to help relieve one or more of the symptoms of cough, colds, nasal or chest congestion and related symptoms." *Block* Abstract. Vicks® VapoRub® ointment and the Block patch function the same way.



The invention of the Rolf Application (shown in the figure above) is strikingly similar, except that the patch (1) is placed closer to the person's nose. Another difference is that Rolf's patch is impregnated with "essential oils." Rolf defines essential oils as "highly odoriferous, liquid components obtained from plant tissue. Essential oils are usually captured by Steam distillation, a process

whose origins can be traced back to ancient Mesopotamia. Unlike ordinary vegetable oils, such as corn and olive, plant essences are highly volatile and will evaporate if left in the open air." Rolf Abstract. Essential oils (15) typically include a mixture of one or more terpenes, esters, aldehydes, ketones, alcohols, phenols, and/or oxides. These functional classes of compounds are responsible for the therapeutic properties and distinct fragrance of the essential oil. *Id*. at [0064]. From Paragraph [0063] to [0073], Rolf lists a myriad of substances that he dubs essential oils. Paragraph [0147] provides a list of preservatives that can be used in his invention. Among them is Benzalkonium Chloride. However, this ingredient is used only as a preservative, which Rolf defines a preservative as any substance which prevents bacterial growth, mold growth, fermentation, and/or decomposition. Paragraphs [0151] - [0152] list many anti-viral agents that may be included on the adhesive patch. Among them is lysine hydrochloride. Rolf proceeds to list 87 embodiments, which are also recited in 87 claims. He also presents 16 example formulations.

Of the 87 claims, three are independent. Claim 86 is a kit claim not relevant to the current validity analysis. Claim 1 reads:

> 1. A method for preventing a respiratory infection in a mammal at risk thereof, the method comprises contacting a live respiratory pathogen at risk of entering the respiratory tract of the mammal with a therapeutically effective amount of an essential oil, such that the live respiratory pathogen is inactivated upon contact with the essential oil, wherein the source of the essential oil is a patch located in the vicinity of the nasal passageway of the mammal.

Claim 80 reads:

> 80. A method for preventing a respiratory viral infection in a mammal at risk thereof, the method comprises contacting a live respiratory virus with a prophylactically effective amount of an essential oil such that the live respiratory virus is inactivated upon contact with the essential oil, wherein the source of the essential oil is a patch located in the vicinity of the nasal passageway of the mammal.

These two independent claims represent the essence of Rolf's teachings.

There is no doubt that Rolf is able to function similarly as Block. Were the active agent to be a vaporizable decongestant such as menthol, Rolf would exhibit improvement over Block because the activated adhesive patch is closer to the individual's nose.

However, the laws of physics do not enable Rolf's invention. Assuming a randomized distribution of harmful or infectious particles in the vicinity of Rolf's patch, some particles will graze by the patch. For argument's sake, assume that Rolf's patch is impregnated with a biocide, those particles that contact the biocide for a sufficient time period may be deactivated. The deactivated particles will then dislodge from the patch, and they will float along with all the other airborne particles. Some will be inhaled, and some will not. In any event, most of the inhaled particles will not be deactivated. Rolf does not CATCH or HOLD the particles, and the KILL function is random and insignificant.

Reviewing Pages 4-6 of the USPTO office action shown in Exhibit G for Rolf's patent application, the examiner provided detailed reasoning explaining why his claims were not enabled. The examiner had serious doubts whether Rolf's invention would work as disclosed in writing.

If Rolf is not enabled for the purpose intended in claims 1 and 80, it is not possible to combine Rolf with Wahi '488 to reproduce method claim 1 or formulation claims 2, 6, and 7.

Moreover, under 35 U.S.C. § 103 a combining prior art references must be read to encompass all of the limitations of the claim under evaluation. Claims 1 and 2 of the '802 Patent encompass the elements of CATCH, HOLD, and KILL, The teachings of Wahi '488 enable the CATCH element. Rolf does not address the HOLD function, and his KILL function is not enabled. Therefore, when combining the teachings of Wahi '488 with those of Rolf, essential elements of Claims 1, 2, 6, and 7 are not present.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wahi '488 alone, or in combination with Rolf.

F. The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wadstrom alone, or in combination with Rolf.

Wadstrom refers to U.S. Patent Application Publication No. 2006/0163149 A1 (hereinafter, "Wadstrom") published by the USPTO on July 27, 2006 of U.S. Patent Application No. 10/559,464 submitted by Torkel Wadstrom, *et.al*. Wadstrom is attached to the Amiji Report as Exhibit 3.

1. Validity Analysis Based On Wadstrom Alone.

Wadstrom discloses his invention in a plurality of "aspects." That aspect most relevant to this analysis is the tenth aspect. However this aspect does not

stand alone. It is directly or indirectly dependent upon the first, second, and third aspects.

> [*A*]*ccording to a first aspect, a product for absorption purposes consisting of an in water insoluble support matrix wherein the support matrix is substituted with a hydrophobic entity which in turn is connected to a positively charged entity (other than said in water insoluble support matrix.*

Wadstrom at [0006]

> *According to a second aspect a method for the manufacture of a product according to the first aspect is provided, wherein a hydrophobic entity connected to a positively charged entity, is attached to a support matrix, preferably using an elimination reaction involving a good leaving group on the hydrophobic entity and a high pH.*

Id.

> *According to a third aspect of the present invention there is also provided a product obtainable by a method according to the second aspect.*

Id.

> *According to a tenth aspect of the present invention there is also provided a nasal spray comprising a product according to the first aspect or third aspect for capturing microorganisms, preferably airborne and/or liquid borne microorganisms, as well as viruses, preferably airborne and/or liquid borne viruses in the nasal cavity.*

Id.

> *The support matrix may further be present in particulate form allowing the application of the product for absorption purposes according to the first or third aspect of the present invention by means of a nasal spray or an ointment.*

Wadstrom at [0007]

The tenth aspect is also recited in claim 64, which depends from Claim 50.

Claim 50: A product for absorption purposes consisting of an in water insoluble support matrix wherein the support matrix is substituted with a hydrophobic entity which in turn is connected to a positively charged entity, other than said in water insoluble support matrix.

Claim 64: A nasal spray comprising a product according to claim 50.

I agree with the author's overview of Wadstrom set forth in Paragraphs 82, 83, and 84 on Pages 33 and 34 of the Amiji Report. Wadstrom's first, second, and third aspect teaches a positively charged formulation connected to a water resistant support matrix. That support matrix may take the form of a cellulose fiber, a face mask, a laboratory filter, a tea bag, *etc.* "The support matrix may further be present in particulate form allowing the application of the product for absorption purposes according to the first or third aspect of the present invention by means of a nasal spray or an ointment." *Wadstrom* at [0006].

Admittedly, the positively charged formulation will attract and CATCH negatively charged particles, and when used in a nasal spray, the formulation in combination with the particulate support matrix will perform that function. However, in Paragraph 109 on Page 45 of the Amiji Report, the author states, "Wadstrom discloses that its claimed formula “efficiently bound” at least two different types of bacteria. (Ex. 3 at [0031].)" However, at [0031], the disclosed support matrix consisted of non-treated and treated (QUAB 342) cellulose fiber filters." The disclosure is silent as to any bonding that occurs when a nasal spray is introduced into an individual's nostrils.

Independent claims 1 and 2 of the '802 Patent recite as follows:

1 A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

a) electrostatically attracting the particulate matter to the thin film;

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:

a) electrostatically attracts the particulate matter to the thin film;

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

As was argued in Section VII *supra* (regarding the '802 Patent), the steps of claim 1 are of a formulation CATCHING, HOLDING, and KILLING harmful particulate matter. The functions of the formulation of claim 2 is to CATCH, HOLD, and KILL the harmful particulate matter.

Also, as discussed earlier, when considering a single prior reference to show claim invalidity, we are talking about anticipation under 35 U.S.C. § 102(a). As such, that single prior art reference must teach every element in the

challenged claim. Claim invalidity may only be established using clear and convincing evidence.

Here, Wadstrom merely teaches CATCHING the contaminants. It is silent regarding HOLDING and KILLING. Because claims 1 and 2 require all three elements to be present, those claims of the '802 Patent cannot be anticipated by Wadstrom alone. Regarding dependent claims 6 and 7, if claim 2 is patentably valid, then claims 6 and 7 must also be valid because they incorporate all of the limitations of claim 2 therein.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wadstrom alone.

2. **Validity Analysis Based On Wadstrom In Combination With Rolf.**

As discussed *supra*, while Wadstrom teaches the CATCH function for harmful particles, it is silent regarding the HOLD and KILL functions. In addition, as argued *supra*, Rolf is not enabled for either CATCH, HOLD, or KILL. Thus, Rolf cannot be combined with Wadstrom to encompass all of the elements of claims 1, 2, 6, and 7 as is required by 35 U.S.C. § 103.

Even if they could be combined, Rolf does not teach HOLDING, and its teachings of KILLING are dubious. The combination of Rolf with Wadstrom does not encompass all of the elements of the challenged claims of the '802 Patent.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wadstrom alone, or in combination with Rolf.

G. <u>The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 alone or Baker '476 alone, or in combination with Rolf, or Khaled, or Rabe, or Katz, or Wahi '790</u>.

This statement at Section XI on Page 74 of the Amiji Report is indefinite and ambiguous. It is very difficult to interpret the statement as it does not take any standard form that the USPTO employs for rejection of claims due to anticipation under 35 U.S.C. § 102(a) or due to obviousness under 35 U.S.C. § 103. I reason that Amiji might mean that both Baker '189 alone and Baker '476 separately anticipate claims 1, 2, 6, and 7 of the '802 Patent under 35 U.S.C. § 102(a). However, the statement of combinations of the other prior art in the alternative is unintelligible. I do not understand precisely what Amiji is saying.

- "Baker '189" refers to U.S. Patent No. 6,559,189 issued to James R. Baker, Jr., *et.al.,* on May 6, 2003, which is attached to the Amiji Report as Exhibit 8.
- "Baker '476" refers to U.S. Patent Application Publication No. 2009/0143476 A1, published by the USPTO on June 4, 2009 for U.S. Patent Application No. 11/928,427 by James R. Baker, Jr., *et.al.*, which is attached to the Amiji Report as Exhibit 9.
- "Khaled" refers to U.S. Patent Application Publication No. 2007/0243237 A1, published by the USPTO on October 18, 2007 for U.S. Patent Application No. 11/404,025 by Mazen Khaled, *et.al.*, which is attached to the Amiji Report as Exhibit 7.
- "Rabe" refers to U.S. Patent No. 6,531,142 issued to Thomas Elliot Rabe, *et.al.* on March 11, 2003, which is attached to the Amiji Report as Exhibit 12.
- "Katz" refers to U.S. Patent Application Publication No. 2002/0006961 A1, published by the USPTO on January 17, 2002 for U.S. Patent Application No. 09/846,722 by Stanley E. Katz, *et.al.*, which is attached to the Amiji Report as Exhibit 13.
- "Wahi '790" refers to U.S. Patent Application No. 2003/0161790 A1, published by the USPTO on August 28, 2003 for U.S. Patent Application No. 10/082,978 by Ashok Wahi, *et.al.*, which is attached to the Amiji Report as Exhibit 14.

  Note that the Wahi '790 patent application issued as U.S. Patent No. 6,844,005 ("Wahi '005"), which is attached to my report as Exhibit I.

1. Validity Analysis Based On Baker '189 Alone.

Baker '189 teaches an antimicrobial composition contained within an oil-water nanoemulsion adjuvant. Among the disclosed embodiments are those where the composition is administered nasally. The nanoemulsion adjuvant is able to form a thin film. The function of the composition is to prevent or treat infection or disease resulting from various microbes. Among the disclosed ingredients are at least one cationic agent and at least one biocide. In at least one embodiment, the composition contains benzalkonium chloride as an ingredient.

However, Baker '189 is silent regarding electrostatic attraction. But, it may be inferred that the presence of a cationic agent in sufficient concentration in some nasally administered embodiment will attract the microorganisms electrostatically. Notwithstanding, Baker '189 is also silent regarding holding the microorganisms in place, and there is no mention of adjusting the adhesion and cohesion of the nanoemulsion to achieve adequate impermeability. This element cannot be inferred from Baker '189 alone.

As argued *supra*, for there to be anticipation under 35 U.S.C. § 102(a), there must be a single reference that teaches all of the elements in the challenged claims. If the reference is silent regarding a single element in the claim, then anticipation is not achieved.

Baker '189 teaches the CATCH and KILL elements. However, it is silent regarding the HOLD element. Holding the harmful particles in place is a critical element in claims 1 and 2. Thus, neither claim 1 nor claim 2 of the '802 Patent is

anticipated by Baker '189. Further, if claim 2 is not anticipated, then claims 6 and 7 cannot be anticipated because dependent claims 6 and 7 incorporate by reference all of the limitations of claim 2.

Thus, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 alone.

1. Validity Analysis Based On Baker '476 Alone.

In Paragraph 101 on Page 42, the Amiji Report states, "Baker '476 filed on October 30, 2007, is a continuation-in-part of the '189 patent and has the same disclosure of the '189 patent in addition to disclosing an embodiment comprising CPC and a benzyl ammonium chloride compound (specifically, alkyldimethyl 1-3,4-dichlorobenzyl ammonium chloride). (Ex. 8, at [0232].)"

Like its parent application, Baker '476 also teaches an antimicrobial composition contained within an oil-water nanoemulsion adjuvant. Among the disclosed embodiments are those where the composition is administered nasally. The nanoemulsion adjuvant is able to form a thin film. The function of the composition is to prevent or treat infection or disease resulting from various microbes. Among the disclosed ingredients are at least one cationic agent and at least one biocide. In at least one embodiment, the composition contains benzalkonium chloride as an ingredient.

However, as with its parent application, Baker '476 is silent regarding electrostatic attraction. But, it may be inferred that the presence of a cationic agent in sufficient concentration in some nasally administered embodiment will

attract the microorganisms electrostatically. Notwithstanding, Baker '476 is also silent regarding holding the microorganisms in place, and there is no mention of adjusting the adhesion and cohesion of the nanoemulsion to achieve adequate impermeability. This element cannot be inferred from Baker '476 alone.

As argued *supra*, for there to be anticipation under 35 U.S.C. § 102(a), there must be a single reference that teaches all of the elements in the challenged claims. If the reference is silent regarding a single element in the claim, then anticipation is not achieved.

Baker '476 teaches the CATCH and KILL elements. However, like its parent application, it is silent regarding the HOLD element. Holding the harmful particles in place is a critical element in claims 1 and 2. Thus, neither claim 1 nor claim 2 of the '802 Patent is anticipated by Baker '476. Further, if claim 2 is not anticipated, then claims 6 and 7 cannot be anticipated because dependent claims 6 and 7 incorporate by reference all of the limitations of claim 2.

Thus, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '476 alone.

3. <u>Combinations with Rolf</u>

As argued *supra*, under 35 U.S.C. § 103, prior art references may be combined if a person of ordinary skill would do so to produce the claimed invention at the effective filing date. Hindsight is impermissible. The '802 Patent may not be used as a template to show obviousness over itself. The references themselves must teach and suggest the combination. However, when combining

the references, the combination must encompass all elements of the challenged claim. The combination may not be silent about any element.

As discussed *supra,* claims 1, 2, 6, and 7 recite the elements of CATCH, HOLD, and KILL. Further, while both Baker '189 and Baker '476 teach CATCH and KILL, neither reference teaches HOLD.

As argued previously, Rolf is not enabled (*see* Exhibit G) for what it attempts to claim. Rolf unsuccessfully attempted to teach and recite the KILL element. Thus, it cannot be combined with either Baker '189 or '476. Yet, notwithstanding lack of enablement, Rolf is silent regarding the HOLD element. Therefore, combining Rolf with either Baker '189 or '476 would not encompass all elements of claims 1, 2, 6, and 7 of the '802 Patent.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 or Baker '476 in combination with Rolf.

4. Combinations with Khaled

Khaled teaches the combination of cationic and anionic polyelectrolytes into a layered thin film that coats and bonds to various substrates (*e.g.,* metal, wood, rubber, plastic, *etc.*). "The positively charged polyelectrolytes and the negatively charged polyelectrolytes arrange themselves into a polyelectrolyte complex, rather than an alternating multi-layer structure, due to the electrostatic attraction between particles, allowing for the formation of a thin film with optimal coverage of the substrate." *Khaled* at Abstract. "The polymeric components form a polyelectrolyte complex, which is a true molecular blend of the individual

polymeric components." *Id.* at [0041]. Khaled's thin film layer is antimicrobial with biocides dispersed within the thin film or dissolved therein. Paragraph [0053] lists a large number of representative biocides. Khaled relates that, "the multilayer containing the antibiotic was placed in a solution containing staphylococcus aureus bacteria. Subsequent investigation of the solution indicated a decrease in growth of the bacteria population compared to a solution containing an uncoated surface." *Id.* at [0052].

Atoms become positively charged cations when they lose electrons. Atoms become negatively charged anions when they absorb electrons. Cationic agents are positively charged, and anionic agents are negatively charged. When interspersed, electrons from the anionic polyelectrolytes migrate to the cationic polyelectrolytes, tending to make the Khaled's thin film electrostatically neutral.

Nowhere does Khaled express or imply that microorganisms are electrostatically attracted to the thin film (*i.e.,* the CATCH function). Further, Khaled is silent as to whether microorganisms are held in place by the thin film (*i.e.*, the HOLD function). However, Khaled says that his antimicrobial film inhibits the growth of a bacteria population (*i.e.,* the KILL function).

Claims 1, 2, 6, and 7 of the '802 Patent encompasses CATCHING, HOLDING, and KILLING. Baker '189 and '476 encompass CATCHING and KILLING, but are silent regarding HOLDING. Because Khaled does not teach HOLDING, the combination of Khaled with Baker '189 or with Baker '476 will not produce a method or formulation that is encompassed by all of the elements of the claims of the '802 Patent that are at issue.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 or Baker '476 in combination with Khaled.

5. Combinations with Rabe

At Page 43 in Paragraph 103 of the Amiji Report, in his overview of the Rabe patent, the author states:

> *Rabe discloses "stabilized electrostatically-sprayable topical compositions" comprising a liquid insulating material (e.g., volatile silicones, volatile hydrocarbons), one or more conductive materials (e.g., C8-C20 isoparaffin, water, alcohols, glycols, polyols and ketones, etc.), a particulate materials and thickeners (e.g., wax or clays). (Ex. 12, at Abstract; 4:12-5:13; 5:14-55; 7:21-30.)*

Further, in Paragraph 104 on the same page, the author states:

> *Sprays can include quatemium/benzalkonium compounds (e.g., Quaternium-18/Benzalkonium Bentonite. (Id., at 8:20-44), Various further anti-microbial agents can also be included. (Id. at 9:11-13.)*

I agree with Amiji's overview of the Rabe patent. Rabe teaches compositions that are used for treating a person's skin and are intended to be applied thereto. Although Rabe's compositions are electrostatically-sprayable, prior to application they do not exhibit electrostatic properties. In the preferred embodiments, the compositions are sprayed onto an individual's skin using a sprayer that imparts a charge to the droplets by applying an electric voltage at the spray nozzle assembly. *Rabe* at 13:53-14:2. The electrostatic charge of the droplets may be either positive or negative (depending on how the voltage is applied), but droplets having a positive charge is preferred. *Id.* at 14:2.

> *How the spray works is generally explained, for example, by explaining that the product is a fine mist of product droplets that are charged so that they stay separated during application and are uniquely attracted to the face versus non-target areas such as the hair, clothing, etc., yet needs no blending. Id.* at 16:59.

Thus, the composition taught by Rabe has no relation to anything taught or claimed in the '802 Patent other than imparting an electrostatic charge to the skin. Further, Rabe teaches alternate application methods.

> *The topical compositions can alternatively be applied to the skin to form the discontinuous films by silk screen techniques or the like, and additionally by using application techniques which provide product deposition via the use of normal forces (i.e., forces perpendicular to the skin surface). Id.* at 18:7.

In addition:

> *In one embodiment, the fluid topical skin product is absorbed into the porous material and then "blotted" onto the skin using forces perpendicular to the skin (as opposed to tangential, or shearing forces). This application technique uses the pore size and pore spacing of the material to create the discontinuous deposition patter. Id.* at 18:55.

Nowhere in Rabe is there any mention of application of an anti-bacterial or an antimicrobial formulation or application to the nasal passages. In cases where Rabe's composition exhibits an electrostatic charge on the skin there may be some electrostatic attraction. However, electrons from the air often deposit on the skin thus causing skin irritation. When there are enough electrons, hairs on the skin will stand erect. A person's skin is normally negatively charged. Imparting a material having a positive electrostatic charge to the skin adsorbs the electrons and neutralizes the skin's natural negative charge. There will be no electrostatic attraction of negatively charged airborne contaminants. Rabe does not exhibit the functions of CATCHING, HOLDING, or KILLING.

As argued *supra*, to show that the combination of Rabe with Baker '189 or Baker '476 makes the '802 Patent's claims 1, 2, 6, or 7 obvious to a person of ordinary skill, the combined references would need to encompass all of the claimed elements, *i.e.*, CATCH, HOLD, and KILL. While Baker '189 and Baker '476 teach CATCH and KILL, they are silent regarding HOLD. Their combination with Rabe does not remedy the situation.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 or Baker '476 in combination with Rabe.

6. Combinations with Katz

At Page 43 in Paragraph 105 of the Amiji Report, the author states:

> *Katz discloses multiple nasal sprays including BAC. (See Ex. 13, at [0078]-[0081]). For example, paragraph [0079] provides that "1.5 fl. oz. (45 ml) of Afrin® moisturizing saline mist solution may be purchased commercially over the counter (Schering-Plough, Memphis, Tenn.). The solution contains water, PEG-32, sodium chloride, PVP, disodium phosphate, sodium phosphate, benzalkonium chloride, and disodium EDTA." (Ex 13, at [0079].)*

While Katz uses benzalkonium chloride as a preservative, it is very dilute (*i.e.,* 1:5000). *Katz* at [0081]. While Katz discloses that his formulations exhibit an antimicrobial effect (KILL), there is no indication that the concentration of benzalkonium chloride is sufficient to exhibit any electrostatic attraction (CATCH). He is silent regarding holding harmful particles in place (HOLD). Katz is silent regarding the CATCH and HOLD functions.

As argued *supra*, to show that the combination of Katz with Baker '189 or Baker '476 makes the '802 Patent's claims 1, 2, 6, or 7 obvious to a person of

ordinary skill, the combined references would need to encompass all of the claimed elements, *i.e.*, CATCH, HOLD, and KILL. While Baker '189 and Baker '476 teach CATCH and KILL, they are silent regarding HOLD. Their combination with Katz does not remedy the situation.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 or Baker '476 in combination with Katz.

7. Combinations with Wahi '790

The Amiji Report listed 33 references that he purported to be prior art that he considered in forming his opinions. *Amiji Report* Pages 8-12. The author listed Wahi '790 as Exhibit 14. He stated, "I understand that none of these references were before the Patent Office during prosecution of the '802 Patent except "Wahi '488" and "Wahi '481." *Id.* at Pg. 12, ¶ 25. However, Wahi '790 is the USPTO publication of U.S. Patent Application No. 10/082,978 by Ashok Wahi, *et.al*. The Wahi '790 patent application issued as U.S. Patent No. 6,844,005 ("Wahi '005"), which is attached to my report as Exhibit I. Wahi '005 was disclosed to the USPTO upon filing of the patent application in an Information Disclosure Statement, and it was considered by Examiner Henley during examination. (*See* Exhibit C, attached hereto.) The first paragraph in Wahi '790 is titled, "INCORPORATIONS BY REFERENCE," while the first paragraph in Wahi '005 is titled, "REFERENCE TO RELATED CASES." Otherwise, the specifications of the two references are identical. The application received a notice of allowance at the first office action on the merits. No

amendments were made to the claims. Therefore, by having considered Wahi '005 during patent prosecution, since Wahi '790 is a virtually identical document, Examiner Henley considered the teachings of Wahi '790 when he allowed the '802 Patent to issue.

Wahi '005 (as well as Wahi '790) was an improvement over Wahi '481 that was made six years later. The primary difference between the two patents lie with the cationic agents used in the latter patent, which provide the source for a stronger electrostatic field. Wahi '005 utilizes poly (dimethyl diallyl ammonium chloride) polymer included in the product in an amount of at least 10% by weight.

The objective of the Wahi '481 and Wahi '005 (*i.e.* '790) products are merely to restrict the flow of airborne contaminants into an individual's nose by inhalation. Both the '005 Patent and the '481 Patent teach that creation of an electrostatic field near an individual's nasal passages can inhibit (or lessen) the number of airborne contaminants that are inhaled by the individual. Nowhere in either the '005 or '481 Patents is it taught that a product is applied to the skin or tissue of the nasal passages. Instead an electrostatic field is created in the vicinity of the person's nose. If the electrostatic field is positively charged, then negatively charged particles will be attracted to the formulation, *i.e.,* they will be caught and will not be inhaled (*i.e.,* the CATCH function). Neither the '005 nor the '481 Patent teaches HOLDING or KILLING. Nothing in the patents teaches that the particles will not be dislodged and inhaled after being CAUGHT. Moreover, nothing in the patents teaches that the particles are KILLED (inactivated and rendered harmless).

Baker '189 and Baker '476 are silent regarding the HOLD function. For any combination with Baker '189 or Baker '476 to successfully present a case for obviousness, the second reference must teach the HOLD function. However, Wahi '790 does not teach the HOLD function. Therefore, the combination of Wahi '790 or Wahi '005 with Baker '189 or Baker '476 cannot render claims 1, 2, 6, or 7 of the '802 Patent obvious.

In addition, Examiner Henley considered Wahi '005 during examination of the application that issued as the '802 Patent. Exhibit C (attached hereto) shows the examiner's initials next to item 16 (Wahi '005). Because a clear and convincing showing is required to invalidate a patent, the fact that the examiner considered this prior art reference and allowed the patent application to issue as the '802 Patent should be given great deference.

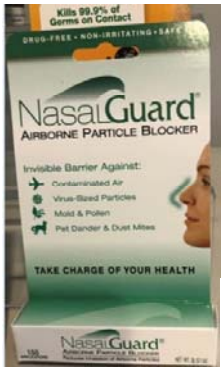
IX. Secondary Consideration - Commercial Success

As stated by the Federal Circuit:

> *evidence of secondary considerations may often be the best probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.*
> *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-40 (Fed. Cir. 1983).

> *Thus when differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field, the decision-maker must consider the obviousness of the new structure in this light. Such objective indicia as commercial success, or filling an existing need, illuminate the technological and commercial environment of the inventor, and aid in understanding the state of the art at the time the invention was made.*
> *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991).

The '802 Patent issued in 2012. On or around that time, Trutek formulated over-the-counter products that were based on the '802 Patent. The products had different brand names and packaging, and they were marketed and sold in the United States and abroad. All products sold in the United States had the '802 Patent number printed on the packaging. The following photographs show some of these products.



The court in *Stratoflex*, 715 F.2d at 1539, has unequivocally stated that for commercial success of a product embodying a claimed invention to have true relevance to the issue of nonobviousness, that success must be shown to have in some way been due to the nature of the claimed invention, as opposed to other economic and commercial factors unrelated to the technical quality of the patented subject matter. Thus, a "nexus is required between the merits of the claimed invention and the evidence offered. If that evidence is to be given substantial weight enroute to [a] conclusion on the obviousness issue."

Since 2012, approximately seven million tubes of the '802 patented products have been sold worldwide. On Amazon.com, a typical price for the NasalGuard Airborne Particle Blocker® is $14.85. Thus, the sales have been substantial. At this point, it is difficult to determine which are initial sales or repeat sales. Clearly, seven million people did not purchase the products. A substantial number must have been repeat sales. The large number of repeat sales indicates satisfaction with the products. Satisfaction is necessarily based on the ability of the product to inhibit harmful particles from infecting the purchaser through nasal inhalation. Harmful particles would be, *e.g.*, pollen, dust, allergens, cold and flu viruses, *etc.* Trutek has done minimal advertising. In my opinion, commercial success of the NasalGuard® products is due to the products' performance according to the '802 Patent.

X. CONCLUSIONS

After reading and understanding the Amiji Report and references to the exhibits thereto, I conclude that the author failed to show by a clear and convincing standard of proof that claims 1, 2, 6, or 7 of the '802 Patent are invalid either under 35 U.S.C. §§ 101, 112, 102(a), or 103. The examiner determined that the subject matter and utility of the claims at issue conform to the requirements of 35 U.S.C. § 101. The examiner also determined that the written description conformed to the requirements of 35 U.S.C. § 112(a). The examiner further determined that the patented claims were enabled. None of the prior art references cited by the Amiji Report as invalidating the claims at issue fail to overcome the presumption of validity according to a clear and convincing standard of proof. Furthermore, when attempting to define a person having ordinary skill in the art, the author actually defined a person having extraordinary skill. That designation is critical because a person of extraordinary skill would make predictions based on prior art, which a person of ordinary skill would not make.

Date: ___August 12, 2022___

Respectfully submitted,

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EXHIBIT A

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"THE EXTRATERRITORIALITY OF UNITED STATES PATENT AND TRADEMARK LEGISLATION" NJSBA MID-YEAR MEETING AND CONVENTION, NOVEMBER 7, 2014, PARIS, FRANCE

"INTERNATIONAL LAW AND INTELLECTUAL PROPERTY: SERVICE OF PROCESS AND DISCOVERY CONSIDERATIONS UNDER THE HAGUE CONVENTION AND TRANSNATIONAL ENFORCEMENT OF JUDGMENTS" NJICLE, DECEMBER 4, 2014, NEW BRUNSWICK, NEW JERSEY

"ETHICAL RELATIONSHIPS: HANDLING CONFLICTS IN CLIENT AND ATTORNEY RELATIONS" NJSBA ANNUAL MEETING AND CONVENTION, MAY 19, 2016, ATLANTIC CITY

"RECENT DEVELOPMENTS IN PROFESSIONAL RESPONSIBILITY AND ETHICS" NJSBA ANNUAL MEETING AND CONVENTION, MAY 18, 2017, ATLANTIC CITY

"AROUND THE SKY-THE LATEST IN AVIATION, *A WEBINAR*, NJ-ICLE, MAY 26, 2022, BROADCAST BY ZOOM

MODERATOR: "STATUTE OF LIMITATIONS CONCERNS IN CRIMINAL CASES"- *A WEBINAR*, NJ-ICLE, JANUARY 24, 2013, BROADCAST FROM NEW BRUNSWICK

BAR RELATED ACTIVITIES: MEMBER: MEMBER, LATER CHAIR, PANEL 6, SUPREME COURT COMMITTEE ON FEE ARBITRATION, DISTRICT XII (2001-2006)

MEMBER: SUPREME COURT COMMITTEE ON ATTORNEY ADVERTISING (FORMER VICE CHAIR 2018/2019)

MEMBER: SUPREME COURT ADVISORY COMMITTEE ON PROFESSIONAL ETHICS

TRUSTEE: NEW JERSEY STATE BAR ASSOCIATION (2007 TO 2013)

TRUSTEE: UNION COUNTY BAR ASSOCIATION (2002 TO 2013)

NEW JERSEY STATE BAR ASSOCIATION TRUSTEE LIAISON AT VARIOUS TIMES TO: CIVIL TRIAL BAR SECTION, HEALTH AND HOSPITAL LAW SECTION, INSURANCE LAW SECTION, INTELLECTUAL PROPERTY LAW SPECIAL COMMITTEE AND WOMEN IN THE PROFESSION SECTION (2007 TO 2013)

MEMBER (PAST AND PRESENT): NEW JERSEY STATE BAR ASSOCIATION, AMICUS STANDING COMMITTEE, DIVERSITY STANDING COMMITTEE, PROFESSIONAL RESPONSIBILITY STANDING COMMITTEE, APPELLATE PRACTICE SPECIAL COMMITTEE, AVIATION LAW SPECIAL COMMITTEE, INTELLECTUAL PROPERTY LAW SPECIAL COMMITTEE

MASTER: RICHARD J. HUGHES AMERICAN INN OF COURT

MASTER: JOHN C. LIFLAND AMERICAN INN OF COURT

MASTER: WILLIAM C. KONNER AMERICAN INN OF COURT

N.J. RULE 1:40 MEDIATOR

ARBITRATOR, MANDATORY NON-BINDING AUTOMOBILE AND PERSONAL INJURY ARBITRATION PROGRAMS OF THE MORRIS AND UNION COUNTY VICINAGES OF THE SUPERIOR COURT OF NEW JERSEY

ALUMNI RELATED ACTIVITIES:

SECOND VICE PRESIDENT, BRITISH SCHOOLS AND UNIVERSITIES CLUB OF NEW YORK (2005-2006), HONORARY SECRETARY (2011-2012)

EXPERIENCE:

(1988 TO PRESENT) SOLO PRACTITIONER; (1984 TO 1988) PARTNER, HAIDRI, GLAZER & KAMEL, PRIVATE PRACTICE CONCENTRATED IN PERSONAL INJURY, AND WORKERS' COMPENSATION PREDOMINANTLY FOR PLAINTIFFS AND PETITIONERS; HANDLED PERSONAL INJURY PROTECTION AND MEDICAL PROVIDERS' COLLECTION ACTIONS AND ARBITRATIONS; ACTED AS ARBITRATOR IN UNINSURED/UNDERINSURED MOTORIST CASES; HANDLED APPELLATE MATTERS.

DECEMBER 1982 TO JUNE 1984

LEVER BROTHERS COMPANY
EDGEWATER, NEW JERSEY
PATENT ATTORNEY

REVIEWED AND EVALUATED PATENT DISCLOSURES. PREPARED AND FILED PATENT APPLICATIONS. ASSUMED RESPONSIBILITIES FOR THE PROSECUTION OF U.S. AND FOREIGN PATENT APPLICATIONS. PREPARED CONSULTING, SECRECY AND LICENSE

AGREEMENTS, AS WELL AS INFRINGEMENT AND VALIDITY OPINIONS.

MAY 1981 TO DECEMBER 1982

TEXACO DEVELOPMENT CORPORATION
WHITE PLAINS, NEW YORK
PATENT ATTORNEY

REVIEWED DISCLOSURES FROM INVENTORS FOR PATENTABILITY, EVALUATED SEARCHES AND DRAFTED PATENT APPLICATIONS, PROSECUTED U.S. AND FOREIGN CASES INCLUSIVE OF PREPARATION AND FILING OF AMENDMENTS, APPEALS, CONTINUATIONS AND FOREIGN OPPOSITIONS.

1972 TO 1981

HASELTINE AND LAKE
NEW YORK, NEW YORK
ASSOCIATE AND DIRECTOR OF TRADEMARK DEPARTMENT

PREPARED AND FILED TRADEMARK APPLICATIONS, OPPOSITIONS, CANCELLATIONS, LICENSING OF TECHNOLOGY AND RECORDING OF LICENSES, INFRINGEMENT, PASSING OFF AND UNFAIR COMPETITION ACTIONS.

1971 TO 1972

W.P. THOMPSON & CO.
LIVERPOOL, ENGLAND
ASSOCIATE

PRINCIPALLY SAME EXPERIENCE AS HASELTINE AND LAKE WITH EMPHASIS ON BRITISH PRACTICE, REGISTERED USER RECORDATIONS AND INCIDENTAL PATENT AND DESIGN MATTERS.

EXHIBIT B

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-09)
Approved for use through 04/30/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	
Examiner Name	
Attorney Docket Number	51900-TRUTEK-009

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	1071015		1913-08-26	Adler, J.	
	2	2237954		1941-04-08	Wilson, W.R.	
	3	2433565		1947-12-30	Korman, A.	
	4	2777442		1957-01-15	Zelano, J.	
	5	3145711		1964-08-25	Beber, A.	
	6	3513839		1970-05-26	Vacante, M.	
	7	4030491		1977-06-21	Mattila, A.	
	8	4052983		1977-10-11	Bovender, C.R.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
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Application Number	
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First Named Inventor	Ashok Wahi
Art Unit	
Examiner Name	
Attorney Docket Number	51900-TRUTEK-009

	9	4267831		1981-05-19	Aguilar, M.	
	10	4401117		1983-08-30	Gershuny, H.	
	11	4789504		1988-12-06	Ohmori, et.al.	
	12	4874659		1989-10-17	Ando, et.al.	
	13	2751906		1953-10-26	Irvine, M.E.	
	14	5468488		1995-11-21	Wahi, A.L.	
	15	5674481		1997-10-07	Wahi, A.L.	
	16	6844005	B2	2005-01-18	Wahi, A.L.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030223934	A1	2003-12-04	Wahi, A.L.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

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Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	
Examiner Name	
Attorney Docket Number	51900-TRUTEK-009

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

EXHIBIT C

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-09)
Approved for use through 04/30/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	1629
Examiner Name	Raymond J Henley III
Attorney Docket Number	51900-TRUTEK-009

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/R.H./	1	1071015		1913-08-26	Adler, J.	
	2	2237954		1941-04-08	Wilson, W.R.	
	3	2433565		1947-12-30	Korman, A.	
	4	2777442		1957-01-15	Zelano, J.	
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	6	3513839		1970-05-26	Vacante, M.	
	7	4030491		1977-06-21	Mattila, A.	
/R.H./	8	4052983		1977-10-11	Bovender, C.R.	

/Raymond J. Henley III/ 08/19/2011

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	1629
Examiner Name	Raymond J Henley III
Attorney Docket Number	51900-TRUTEK-009

/R.H./	9	4267831		1981-05-19	Aguilar, M.	
	10	4401117		1983-08-30	Gershuny, H.	
	11	4789504		1988-12-06	Ohmori, et.al.	
	12	4874659		1989-10-17	Ando, et.al.	
	13	2751906		1953-10-26	Irvine, M.E.	
	14	5468488		1995-11-21	Wahi, A.L.	
	15	5674481		1997-10-07	Wahi, A.L.	
/R.H./	16	6844005	B2	2005-01-18	Wahi, A.L.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/R.H./	1	20030223934	A1	2003-12-04	Wahi, A.L.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

/Raymond J. Henley III/ 08/19/2011

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	1629
Examiner Name	R.J.Henley III
Attorney Docket Number	51900-TRUTEK-009

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Raymond J. Henley III/	Date Considered	08/19/2011

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

EXHIBIT D

MAXNEEMAN
CONTRACT RESEARCH
Improving... life

A Multi-Center Study to Determine
The Safety and Efficacy of
Trutek's "Multi Acting Nasal Particle Blocker (MAPB)"
as a Preventive Treatment for Cold and Flu

Clinical Study Report

07 March 2012

CLINICAL STUDY REPORT

STUDY ID:	TTK-MAPB-MN01
SPONSOR:	Trutek Corp. 281 East Main Street Somerville, NJ 08876 United States of America Tel.: +1 908 685 1111
INVESTIGATIONAL DEVICE:	Multi Acting Nasal Particle Blocker
Study Initiation Date (First Subject Enrolled):	02 August 2011
Study Completion Date (Last Subject Completed):	12 November 2011
Name & Contact Details of Sponsor's Signatory:	Vir Narula Chief Operating Officer Trutek Corp. 281 East Main Street Somerville, NJ 08876 United States of America Tel.: +1 908 685 1111
Report Date:	7 March 2012

Confidentiality Statement

2 SYNOPSIS

Name of Company: Trutek Corp. **Name of Product:** Multi Acting Nasal Particle Blocker (MAPB) gel		*(For National Authority Use only)*
Title of the Study:	A Randomized, Prospective, Open label, Parallel group, Comparative, Multi-Center Study to Determine the Safety and Efficacy of Trutek's device "Multi Acting Nasal Particle Blocker (MAPB)" as a Preventive Treatment for Cold and/or Flu.	
Investigators:	The list of Investigators is presented in Appendix 3.	
Investigation Sites:	Three sites, one in Gurgaon and two in Jaipur, in India were selected for this study.	
Study Period:	Date of first subject enrolled: 02 August 2011 Date of last subject completed: 12 November 2011	
Objectives:	The primary objective of the study was: • To evaluate the efficacy of MAPB nasal application gel in the prevention of the common cold and/or flu The secondary objective was: • To evaluate the safety of MAPB nasal application gel in the prevention of the common cold and/or flu	
Methodology:	Randomized, prospective, open label, parallel group, comparative, multi-center study with two groups Group A: Active treatment with MAPB gel Group B: No treatment control group	
Total Number of Subjects:	Planned: 600 healthy subjects (300 subjects each in Group A and Group B)	Randomized: 600 healthy subjects (300 subjects each in Group A and Group B)
Evaluated:	Efficacy: 600 healthy subjects (300 subjects each in Group A and Group B)	Safety: 600 healthy subjects (300 subjects each in Group A and Group B)
Diagnosis and Criteria for Inclusion:	Subjects who fulfilled the following criteria were considered for enrollment into the study: 1. Male or female from 18 years to 70 years of age. 2. Willing to sign written informed consent form. 3. Willingness to comply with the test procedure.	
Investigational Device:	Multi Acting Nasal Particle Blocker manufactured by Trutek Corp. is a patent pending topical gel that filters airborne particles from entering the nasal passages.	
Duration of Administration:	MAPB gel was recommended to be applied 4 to 6 times per day for 8 weeks as directed in the package insert.	
Duration of Treatment:	The study period was for approximately 8 weeks (57 days) with a total of 2 visits, on Day 0 and Day 57, to the investigation site and 3 intermediate phone calls with the Investigator.	

Name of Company: Trutek Corp. **Name of Product:** Multi Acting Nasal Particle Blocker (MAPB) gel	*(For National Authority Use only)*
Reference Therapy:	Control group (Group B) was given no treatment.
Primary Endpoint:	The primary study endpoint was: • Percentage of subjects that were cold and/or flu free in the treatment group at the end of study as compared to the subjects who were cold and/or flu free in the no treatment group
Secondary Endpoints:	The secondary study endpoints were: • Incidence of treatment related adverse events
Statistical Methods:	**Sample Size Calculation** The sample size calculation was based on the detection of difference between two proportions. Assuming the cold and/or flu free subject rates in no treatment group (Group B) and MAPB treatment group (Group A) as 85% and 94%, respectively, detecting a difference of 9% with 95% confidence (two sided 5% level of significance) and with 90% power would require 264 subjects approximately in each group. Adjusting for anticipated 11% dropout rate and balanced randomization, a total of 594 subjects in 1:1 ratio were to be enrolled in the study. The chi-square test for proportions with continuity correction was used for these calculations. The descriptive statistics for continuous variables was presented with number (n) of non-missing observations, mean, standard deviation, median, minimum, and maximum. For categorical data, descriptive statistics was presented with number of exposed subjects, and number (n) with percentage of observations in the various categories of the endpoint, where percentage was based on the exposed subjects. Statistical significance was declared if the two-sided probability value was ≤ 0.05. For efficacy analysis, logistic regression model with treatment group as independent factor was used to compare the subjects at the end of the study. The variables, which can have influence on the cold and/or flu, were taken into consideration by using these factors in logistic regression analysis. P-values, odds ratios and corresponding 95% confidence intervals were reported. Additionally, chi-square test/Fisher exact test (small expected frequency) was used to compare the 'treatment' and the 'no treatment' groups at 5% level of significance.
Summary of Efficacy Results:	• Statistically significant higher number of subjects with cold and/or flu free status was observed in Group A than Group B at the end of the study on Day 57 • The probability of cold and/or flu was approximately 3 times higher in Group B than Group A
Summary of Safety Results:	• No Serious Adverse Device Effects (SADEs) or Serious Adverse Events (SAEs) were observed or reported in the study • Two subjects reported Adverse Device Effects (ADEs) where one reported mild sneezing and another reported vomiting. As per sole discretion of the Investigator, these Adverse Events (AEs) were

	considered to have probable and possible relationships to treatment, respectively • In both the cases there was no recurrence of the event. Hence, the subjects continued to apply MAPB gel and went on to complete the study unhindered for total study duration of 8 weeks
Conclusions:	Six hundred healthy subjects were enrolled in this prospective, open label, parallel group, comparative, multi-center study and were randomized 1:1 to either MAPB or no treatment group. The objective of the study was to evaluate the efficacy and safety of MAPB gel in prevention of cold and/or flu. Three hundred subjects randomized to Group A were instructed to apply MAPB gel 4 to 6 times a day for a period of 8 weeks and the remaining 300 subjects randomized to Group B were not given any treatment and served as the control group. At the end of study (8 weeks), 295/300 (98.3%) subjects using MAPB gel were cold and/or flu free; whereas 285/300 (95%) subjects not on any treatment were cold and/or flu-free. This difference was of statistical as well as of clinical significance. Subjects of Group B had 3 times higher probability of getting cold and/or flu than subjects of Group A. In terms of safety, none of the subjects reported any SAEs or SADEs. Two subjects in Group A reported ADE where one had sneezing and another subject had vomiting. Both the ADEs were of mild intensity. As per sole discretion of the Investigator, these ADEs were considered to have probable and possible relationships to treatment, respectively. There was no recurrence of the event in both the subjects. Hence, both of them continued to apply MAPB gel and went on to complete the study unhindered for total study duration of 8 weeks. In conclusion, MAPB nasal application gel was considered as an efficacious and safe gel in prevention of common cold and/or flu in healthy subjects.
MNI Signatures	07-MAR-2012 **Shekar Sunkoju,** Biostatistician, Max Neeman International
	Bhattacharya. 7 March 2012 **Priyanka Bhattacharya** Medical Writer, Max Neeman International
	S. Anwar 7/March/12 **Dr. Shariq Anwar** Director, Operations Max Neeman International
Date of Report:	07 March 2012

EXHIBIT E

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/467,271	05/16/2009	Ashok Wahi	51900-TRUTEK-009	7676

34325 7590 08/25/2011

STANLEY H. KREMEN
4 LENAPE LANE
EAST BRUNSWICK, NJ 08816

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
08/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@patentsgroup.com

Office Action Summary	Application No.	Applicant(s)	
	12/467,271	WAHI, ASHOK	
	Examiner	Art Unit	
	RAYMOND HENLEY III	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/16/2009 and papers subsequent thereto*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-23* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-23* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/16/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-23 ARE PRESENTED FOR EXAMINATION

Applicant's Information Disclosure Statement filed May 16, 2009 has been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08, (3 sheets), the cited references have been considered.

Overcoming the Rejection Below

In order to overcome the rejection set forth *infra*, it is suggested that Applicant consider amending claims 1, 2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for, at the most, inhibition of infections, does not reasonably provide enablement for the prevention of the same, (see claims 1, 2 and 8; and thus the claims dependent therefrom). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that an infection, which is taken to mean the introduction of an infectious element through the outside of a given host and into the system of such host, (see MPEP § 2113; terms given their broadest reasonable interpretation), may be prevented, (which again, given its broadest, reasonable interpretation), i.e., a material is ever kept from introduction into the system of a host, is doubted because the present claims merely recite a pharmacological composition while an effective prevention against the introduction of an infectious material into a host, especially where such material does not cause any pathology, would require that the exterior system of the host to be completely blocked so as to preclude any infectious material passing through such system and arriving within the system of the host.

In reading the present specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not, may be **inhibited** rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host.

As indicated above, the term "preventing" is here being interpreted as being synonymous with a circumstance such as where a vaccine is administered against a pathogen and the host to whom such was administered does not suffer from the pathogen's effect even when present in the host's system. As such the term "preventing" circumscribes a circumstance of almost absolute success. Because such success is not reasonably possible with the treatment of most infectious diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as encompassed by the present claims, the specification, which lacks an objective showing where prevention is actually manifest, is viewed as lacking an enabling disclosure of the same.

The Examiner notes that the term "prevent" is not *necessarily* synonymous with "cure" or the action of a vaccine, but such interpretation is proper given that "During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)." (MPEP § 2111).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND HENLEY III whose telephone number is (571)272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner
Art Unit 1629

August 19, 2011

EXHIBIT F

CLAIMS

I claim:

1. A method for electrostatically preventing harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
   a) electrostatically attracting the particulate matter to the thin film;
   b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
   c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.
2. A formulation for electrostatically preventing harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
   a) electrostatically attracts the particulate matter to the thin film;
   b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
   c) inactivates the particulate matter and renders said particulate matter harmless.

EXHIBIT G

Interview Summary	Application No.	Applicant(s)	
	10/458,078	ROLF, DAVID	
	Examiner	Art Unit	
	Isis Ghali	1615	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Isis Ghali*. (3)_____.

(2) *Mr. Gary Speier*. (4)_____.

Date of Interview: *24 May 2006*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Attorney indicated that no repose to the office action mailed 11/09/2005 has been filed*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Isis Ghali

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/458,078	06/10/2003	David Rolf	240.079US1	9269

21186 7590 11/09/2005

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/458,078	ROLF, DAVID	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-87 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-87 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-87 are pending and included in the prosecution.

Specification

1. The use of the trademark "Vilmed" and "Q-15" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim21-30 of U.S. Patent No. 6,090,403. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to method for treating (or preventing) respiratory infection using patch comprising backing layer and formulation comprising essential oils positioned in or on the backing layer. The claims of the issued patent are directed to method for relieving cough or bronchial irritation using composition comprising essential oils on a foraminous carrier. It is anticipatory type double patenting rejection since the patented claims anticipate the present claims.

5. Claims 1-87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/300,559. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to method for treating (or preventing) respiratory infection using patch comprising backing layer and formulation comprising essential oils positioned in or on the backing layer. The claims of the copending Application 10/300,559 are directed to patch

comprising essential oils positioned on or in a backing layer and used to treat bronchitis and asthma. Therefore, the present claims and the claims of the copending applications are directed to the same subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-81, 84, 85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the

examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is method for preventing respiratory infection using patch comprising essential oils. The specification does not enable the prevention of respiratory infection in susceptible patients.

The breadth of the claims: The claims are broad. The claims encompass prevention of respiratory infection in susceptible patients at risk, and the burden of enabling prevention of respiratory infection would be greater than that of enabling a treatment due to the need of additional testing and screening to those humans susceptible to such infection. The prevention of respiratory infection may or may not be addressed by the administration of the instant patch. Further, the claims encompass a wide class of essential oils and many respiratory infections.

The state of the prior art: The state of the art does not recognize the administration of essential oils to prevent respiratory infection as required in the instant claims. The state of the art recognizes the treatment of respiratory infection, but not its cure.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on how to prevent the respiratory infection is absent. Guidance for treatment of respiratory infection is provided, however, no evidence that respiratory infection is prevented is provided. It is not obvious from the disclosure of treatment of respiratory infection using essential oils if the prevention of respiratory infection will be

achieved. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to completely preventing respiratory infection by using the instant patch makes practicing the claimed invention unpredictable in terms of the prevention of the infection.

The presence or absence of working examples: No working examples to show preventing respiratory. Therefore, the specification has enabled treating respiratory infection, but not its prevention or cure.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant method for treating respiratory infection using the claimed patch without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner and as set forth the burden of enabling prevention of respiratory infection would be greater than that of enabling a treatment due to the need of additional testing and screening to those humans susceptible to such infection.

For examination purposes, the term "preventing" will be interpreted as "treating" respiratory infection.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 7, 46, 47, 67-69 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding to claim 7, the claim is confusing as it contains angina and mumps listed within the respiratory infections while these disorders are not respiratory infections. Angina is a thrombovascular disease caused by coronary arteries spasm or occlusion and not an infectious conditions. Mumps is infection of the salivary glands which is part of the digestive tract.

Claims 46, 47, 67-69 contain the trademark/trade name Vilmed and quat-15. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe fluorocarbon and preservative, accordingly, the identification/description is indefinite.

Regarding claim 78, the claim recite that "the source of essential oil is located within 6 inch of the mammal" and it is not clear what spot the patch will be 6 inch from?

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-8, 20-22, 32-37, 41-43, 71, 78-83 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 86/02270 ('270).

The present claim 1 recites treating respiratory infection using patch comprising an essential oil.

WO '270 discloses dressing comprising formulation for relieving cough comprising eucalyptus oil impregnated into a carrier of gauze, cotton or cloth and covered by a removable protective layer (page 4, lines 7-16; page 5, lines 17-20, 24). The dressing further comprising acrylate adhesive (page 5, lines 14-16). The essential oil is present in an amount ranging from 5-100% (page 6, lines 4-7). The formulation exerts its effect by the route of evaporation inhalation (page 3, lines 17-18). The formulation is effective against infection, bronchitis, and pneumonia (page 10, lines 4, 20, 25-27; page 11, lines 9-18).

12. Claims 1-15, 17-25, 28-37, 41-43, 59, 78-83 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,090,403 ('403).

The present claim 1 recites treating respiratory infection using patch comprising an essential oil.

US '403 discloses method to treat cold and cough using patch comprising essential oil the wherein the patch to be applied to the face, neck or chest to allow evaporated essential oils to be available to the natural inhalation through the nose or mouth (abstract). The patch comprising formulation comprising the essential oils and a carrier (col.2, lines 12-36). Essential oils included eucalyptus and peppermint (col.2, lines 61-65). The formulation further comprises 0.5-30% acrylic adhesive, 5-50% karaya gum, 44% glycerin (solvent), and water (col.3, lines 20-25; col.7, lines 63-67; col.8, lines 1-4, 15-20, 32-40). The carrier layer that can be porous to allow escape of the moisture or non-porous (col.2, lines 50-60). The carrier layer is typically a flexible sheet of open cell polyurethane foam, polyethylene, nonwoven fabric or cloth (col.4, lines 61-65).

13. Claims 1-9, 11-16, 19-22, 32-43, 52, 53, 61, 65, 71, 78-83 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,244,265 ('265).

The present claim 1 recites treating respiratory infection using patch comprising an essential oil.

US '265 discloses nasal strip or patch to treat cold and congestion comprising flexible backing and adhesive formulation comprising aromatic medication that can be

consumed by inhalation through the nose (abstract; col.4, lines 24-32; col.5, lines 44-47; col.16, lines 49-60). The adhesive formulation comprises acrylate or acrylic adhesive (col.7, lines 15-30). The formulation further comprising fragrance such as lemon fragrance, antiviral agents such as chloride containing agents, antimicrobial, vitamin E (col.5, lines 52-54; col.10, lines 15-17; col.11, lines 38-63, col.12, lines 1-3). Preferred aromatic medication is eucalyptus oil, peppermint oil and menthol (col.11, lines 19-25). The backing layer is porous permits the passage of air and moisture made of melt blown fibers of polyethylene or woven or nonwoven material and may contain fibers or material that improve resiliency (sizing agent) (col.7, lines 1-13, 58-67). The patch further comprising release liner (col.9, lines 13-15).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 9-19, 23-31, 38-40, 44-70, 72-77, 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '270 in view of US 5,536,263 ('263).

The teachings of WO '270 are discussed above. However, WO '270 does not teach material of the backing, the amount of the adhesive, the solvent and its amount,

the karaya gum and its amount, the fragrance, the sizing agents, the skin protectant, the polyhydric alcohol, the additional antimicrobial agent, and the kit comprising mask.

The claimed amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

All the additional ingredients are well known in the art and it is within the skill in the art to use them in a conventional patch. The mask is known to deliver respiratory treatment.

US '263 teaches patch comprising porous flexible backing and formulation applied to the backing that solidify on the backing and permits sustained release comprising 3.3% eucalyptus oil, acrylic adhesive, solvent such as propylene glycol or glycerin, more than 20% karaya gum, and 0.2% quaternimum-15 (abstract; col.2, lines 2-9, 29-31; col.5, lines 26-28; col.6, lines 35-37; col.8, line 50-col.10, line 32). The backing comprising water-insoluble material and sizing agent, and is made of polyester fibers, cotton fibers, or cellulose fibers so it provides the required strength and integrity to the patch and conforms to the body contours therefore better tolerated by patients and more unobtrusive and allow moisture from the skin to evaporate to the atmosphere (col.1, lines 60-65; col.3, lines 1-29; col.5, lines 65-67). The patch further comprises a release liner (col.4, line 62).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat respiratory infection using patch comprising backing and formulation comprising essential oils as disclosed by WO '270 and add quat-15 and polyethylene glycol as disclosed by US '263 motivated by the teaching of US '263 that

composition comprising these ingredient provides sustained release of the active agent, and further replace the backing with a porous backing of fibers comprising sizing agent as disclosed by US '263, motivated by the teaching of US '263 that this kind of backing material provides the required strength and integrity to the patch and conforms to the body contours therefore better tolerated by the patient and more unobtrusive, with reasonable expectation of having patch comprising porous backing made of fibers of polyester and formulation comprising essential oils and quart-15 wherein the patch provides sustained release of the essential oils and has the required strength and integrity to conforms to the body contours wherein the patch is better tolerated by the patient and more unobtrusive.

16. Claims 16, 26, 27, 38-40, 44-58, 60-77, 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '403 in view of US '263.

The teachings of both references are discussed above. However, US '403 does not teach the backing made of fibers, the solvent and its amount, the fragrance, the specific sizing agents, the skin protectant, the polyhydric alcohol, the additional antimicrobial agent, and the kit comprising mask.

The claimed amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

All the additional ingredients are well known in the art and it is within the skill in the art to use them in a conventional patch. The mask is known to deliver respiratory treatment.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat respiratory infection using patch comprising backing and formulation comprising essential oils as disclosed by US '403 and add quat-15 and polyethylene glycol as disclosed by US '263 motivated by the teaching of US '263 that composition comprising these ingredient provides sustained release of the active agent, and further replace the backing with a porous backing of fibers comprising sizing agent as disclosed by US '263, motivated by the teaching of US '263 that this kind of backing material provides the required strength and integrity to the patch and conforms to the body contours therefore better tolerated by the patient and more unobtrusive, with reasonable expectation of having patch comprising porous backing made of fibers of polyester and formulation comprising essential oils and quart-15 wherein the patch provides sustained release of the essential oils and has the required strength and integrity to conforms to the body contours wherein the patch is better tolerated by the patient and more unobtrusive.

17. Claims 10, 17, 18, 23-31, 44-51, 54-60, 62-64, 66-77, 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '265 in view of US '263.

The teachings of both references are discussed above. However, US '265 does not teach the non-porous backing or the open cell foam backing, the amount of the adhesive, the solvent and its amount, the specific sizing agents, the polyhydric alcohol, the specific additional antimicrobial agent, and the kit comprising mask.

The claimed amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

All the additional ingredients are well known in the art and it is within the skill in the art to use them in a conventional patch. The mask is known to deliver respiratory treatment.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat respiratory infection using patch comprising backing and formulation comprising essential oils as disclosed by US '265 and add quat-15 and polyethylene glycol as disclosed by US '263 motivated by the teaching of US '263 that composition comprising these ingredient provides sustained release of the active agent, and further replace the backing with a porous backing of fibers comprising sizing agent as disclosed by US '263, motivated by the teaching of US '263 that this kind of backing material provides the required strength and integrity to the patch and conforms to the body contours therefore better tolerated by the patient and more unobtrusive, with reasonable expectation of having patch comprising porous backing made of fibers of polyester and formulation comprising essential oils and quart-15 wherein the patch provides sustained release of the essential oils and has the required strength and integrity to conforms to the body contours wherein the patch is better tolerated by the patient and more unobtrusive.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

EXHIBIT H

US006090403A

United States Patent [19]

Block et al.

[11] **Patent Number: 6,090,403**

[45] **Date of Patent: Jul. 18, 2000**

[54] **INHALATION THERAPY DECONGESTANT WITH FORAMINOUS CARRIER**

[75] Inventors: **Leslie L. Block**, Chaska; **David J. W. Goon**, Bloomington; **David Rolf**, Eden Prairie, all of Minn.

[73] Assignee: **LecTec Corporation**, Minnetonka, Minn.

[21] Appl. No.: **09/135,104**

[22] Filed: **Aug. 17, 1998**

[51] **Int. Cl.**[7] **A61L 15/16**; A61F 13/02

[52] **U.S. Cl.** **424/447**; 424/445; 424/448

[58] **Field of Search** 424/443, 445, 424/447, 448

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Primary Examiner—Carlos A. Azpuru

Attorney, Agent, or Firm—Schwegman, Lundberg, Woessner & Kluth P.A.

[57] **ABSTRACT**

A vaporizable decongestant is supported and stabilized on a flexible foraminous carrier composed typically of open-cell plastic foam, cloth or other fibrous material such as non-woven fabric. The term "foraminous" herein is intended to refer to a substance or medium containing minute openings or perforated by many minute apertures. The decongestant is placed on the surfaces within the interstices and minute apertures or on fibers from which the foraminous carrier is formed. Vaporization of the inhalable decongestant is facilitated by providing the potential for greatly increasing its exposed surface area. Distributing the decongestant composition over the large, expanded surface within the foraminous carrier is beneficial in enhancing both the volatilization and evaporation of the decongestant agent. It also prolongs the useful life of the product. Once vaporized, the aromatic decongestant is available for natural inhalation through the nose or mouth to help relieve one or more of the symptoms of cough, colds, nasal or chest congestion and related symptoms. The foraminous carrier is preferably provided in the form of a patch or sheet that is bonded to the skin to serve as a supporting base for the active decongestant agent. The patch defining the carrier is typically adhesively bonded to the upper part of the body, e.g. on the face, neck or chest, in a location where the decongestant is liberated into the air and can be inhaled through the mouth or nose.

41 Claims, 5 Drawing Sheets

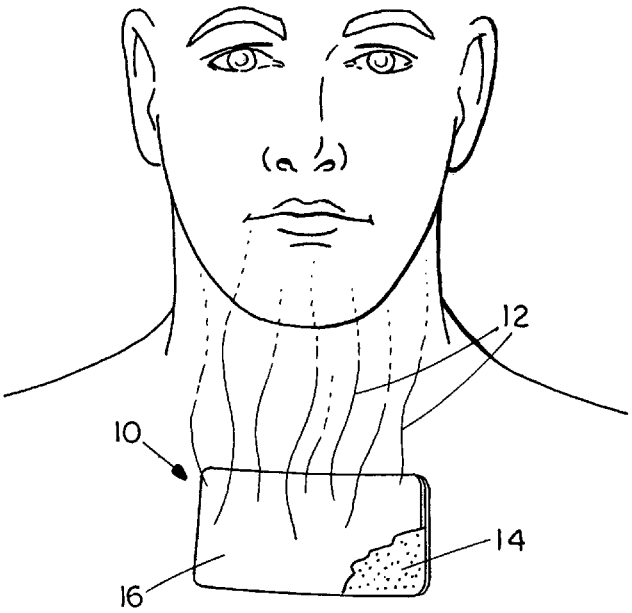


FIG. 1

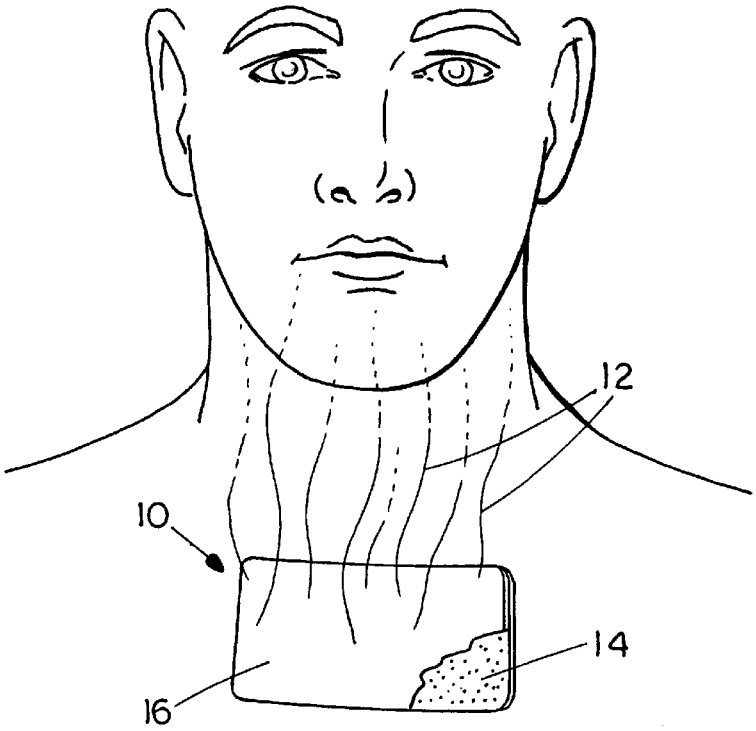


FIG. 2

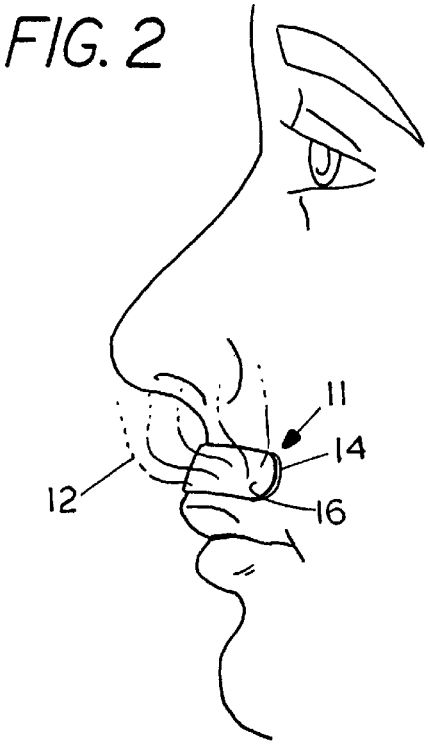


FIG. 3

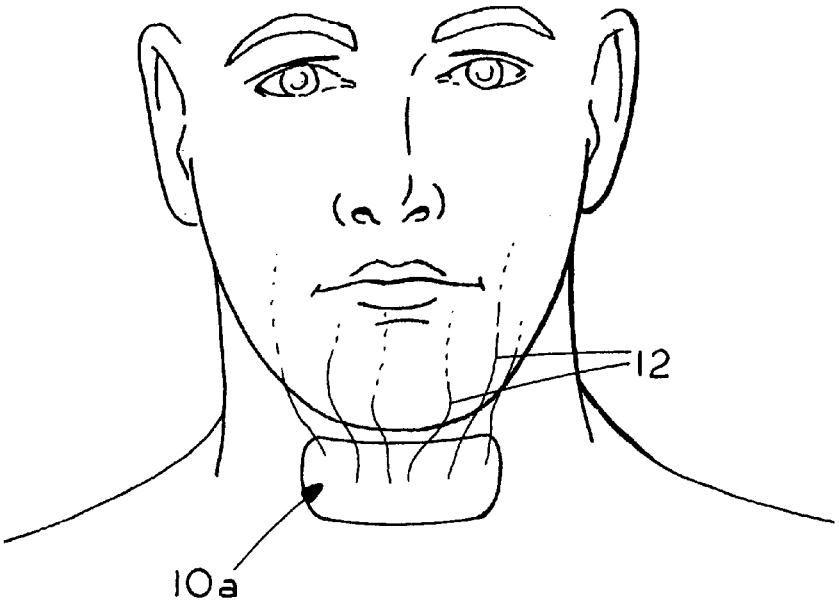


FIG. 4

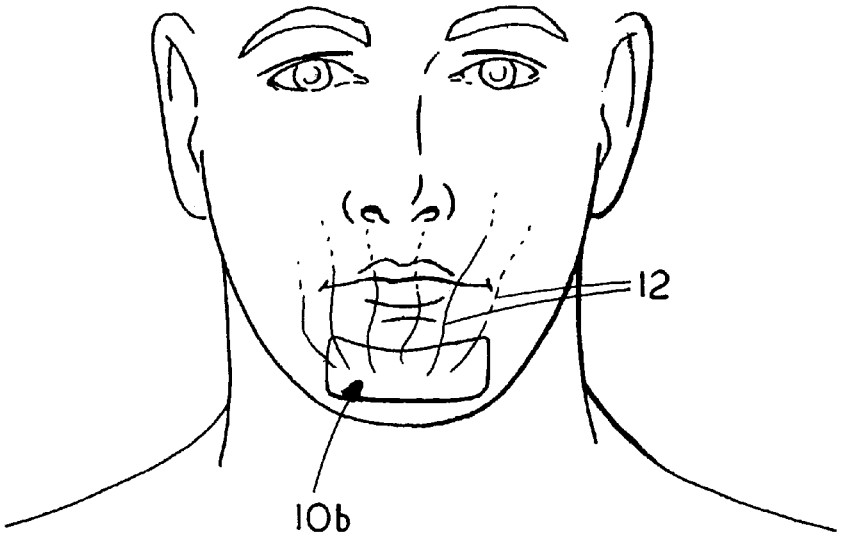


FIG. 5

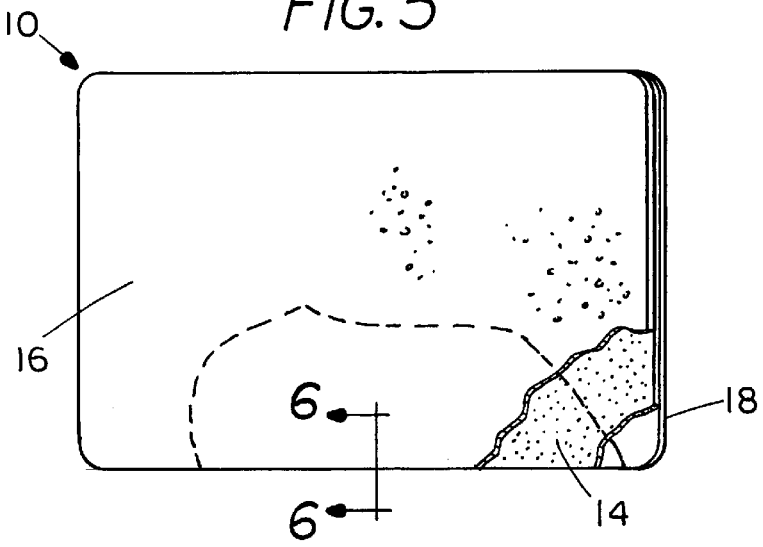


FIG. 6

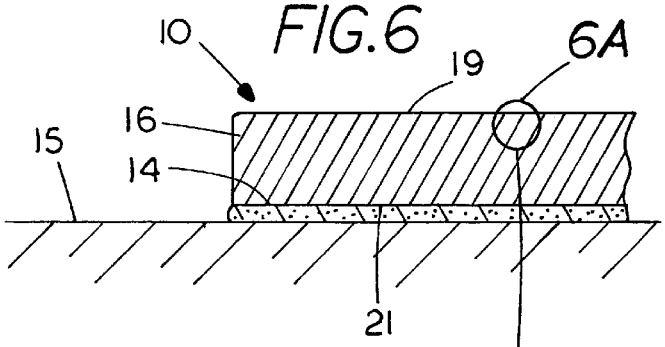


FIG. 6A

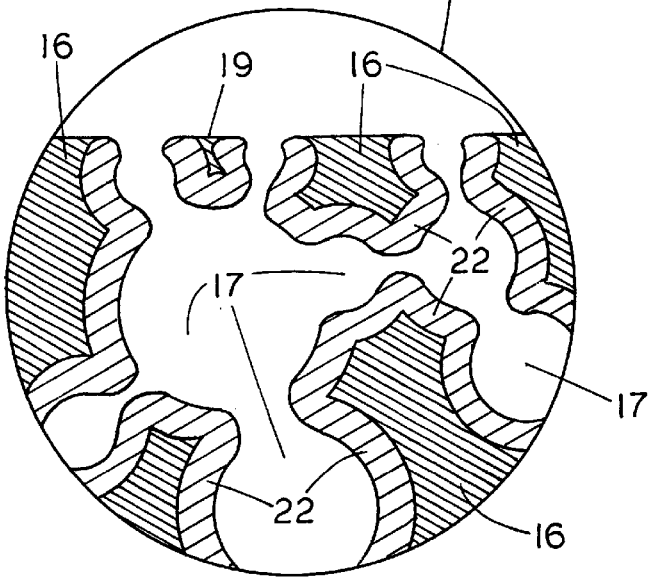


FIG. 7

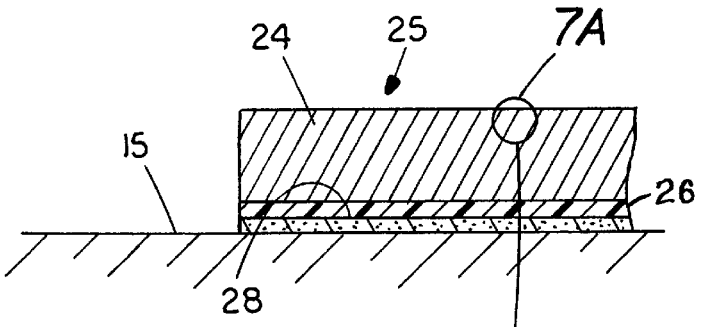


FIG. 7A

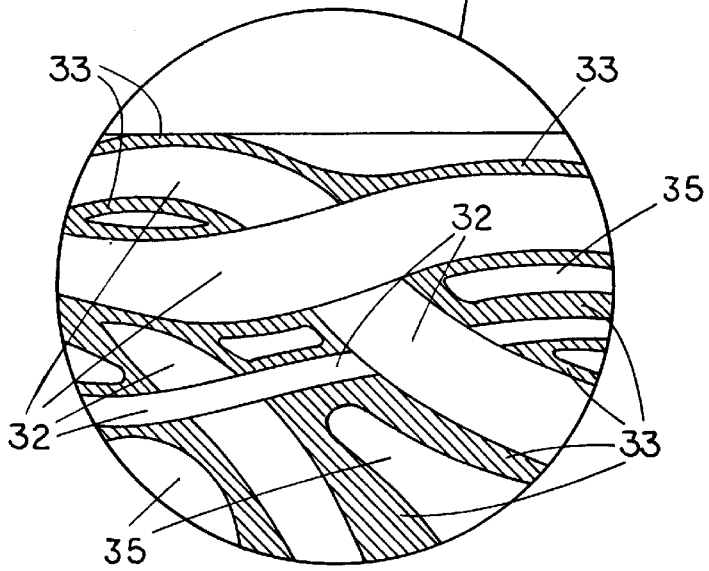
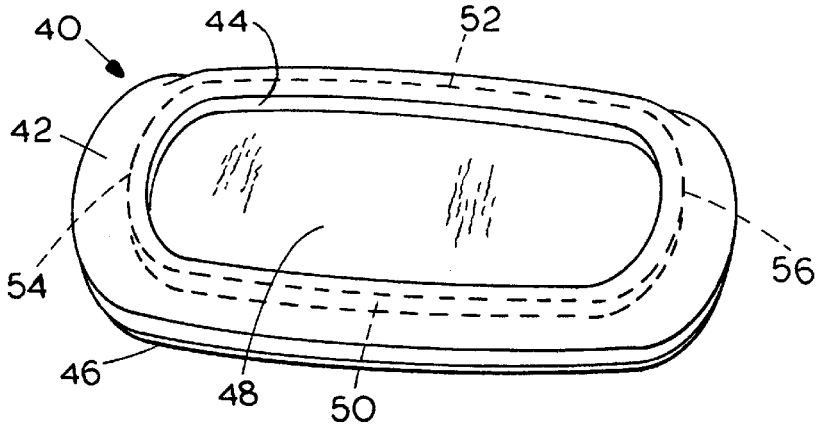


FIG. 8



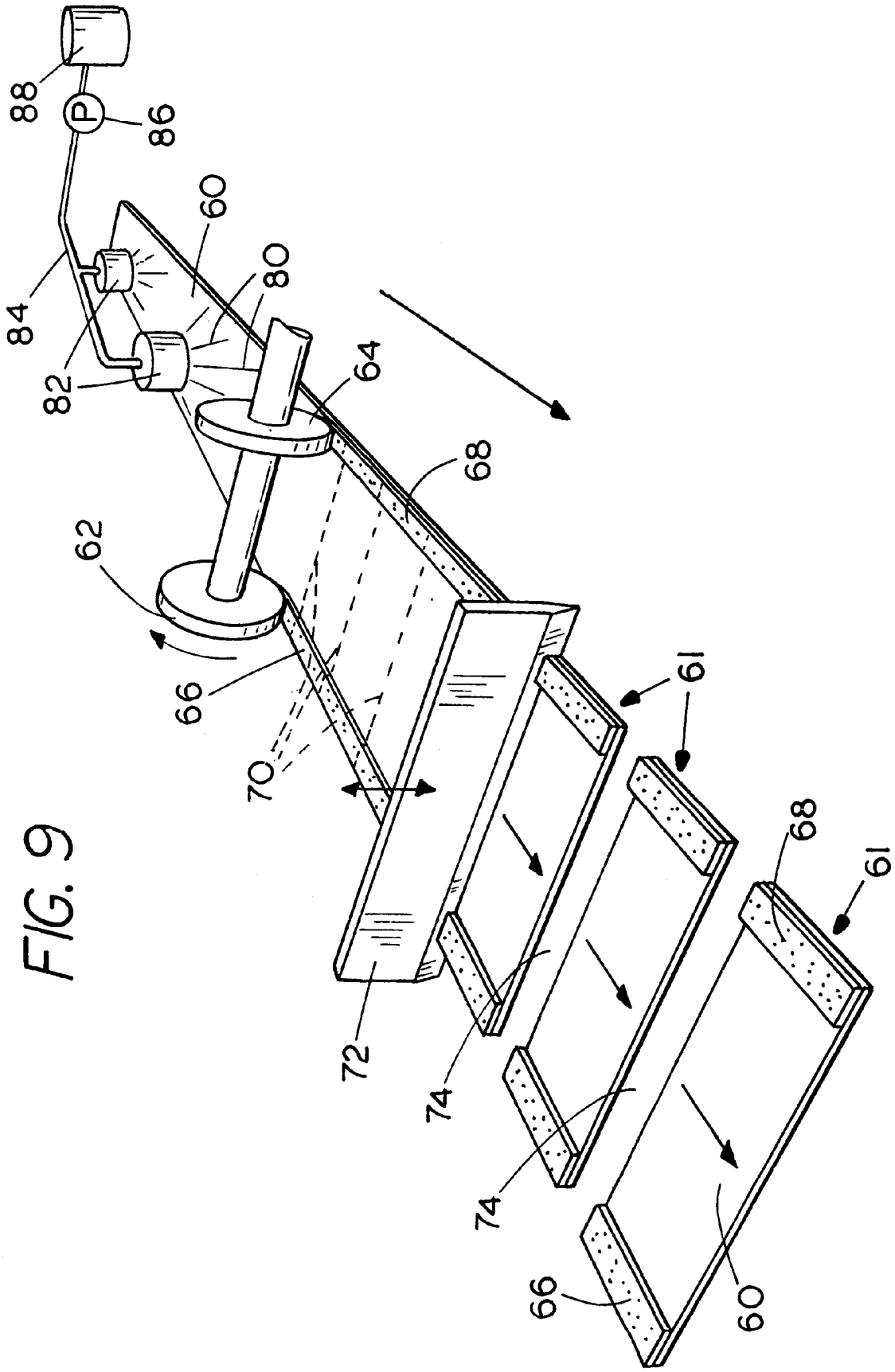


FIG. 9

INHALATION THERAPY DECONGESTANT WITH FORAMINOUS CARRIER

FIELD OF THE INVENTION

This invention relates to inhalation therapy and more particularly to the inhalation of decongestants for the relief of nasal congestion, cough, colds or chest congestion.

BACKGROUND OF THE INVENTION

About $1.5 billion per year are estimated to be spent in over-the-counter cold medications in the United States. Inhalation therapy employed for the relief of bronchial spasms, bronchial asthma, bronchitis, the relief of cough, colds and nasal congestion as carried out at the present time requires a pressurized can for expelling a given quantity of an aerosol containing a therapeutic agent such as epinephrine. These containers are expensive, require the patient to follow instructions carefully, and must be administered according to a set schedule. Other vaporizers that are sometimes used are even more complex. Electric nebulizers and hot water vaporizers are examples. In addition to the expense, these products cannot be used out of doors or away from home. Consequently, they are unsuitable for use at the work place or while riding in a car. Because of these problems, decongestants such as camphor which are intended to be applied to the throat and chest are sometimes used to help relieve cough or cold symptoms. A decongestant of this type typically has a petrolatum base, giving it the consistency of petroleum jelly. One such product is sold under the trademark VICK'S VapoRub®. A similar topical aromatic composition is described in U.S. Pat. No. 5,322,689 but without a high level of petrolatum. Instead, a carboxylic acid copolymer is used. This composition, however, has the consistency of a fluid like the VICK'S product and is also applied topically. These products have significant drawbacks. Petroleum-based fluids are greasy and tend to be spread onto areas that are not intended. In addition, the fingers of the user must be dipped into the fluid product and, consequently, the product gets onto hands, on clothing, and can even be spread to areas where it can cause irritation, such as the nasal mucosa or the eyes. When applied by a healthcare worker, the smell of the decongestant can be carried away on hands and clothing. Moreover, because of the fluidity of such these products, they soon rub off onto the user's clothing and bed linens.

Another shortcoming of prior decongestants is the limitation on the rate of evaporation of the active aromatic substances. A large portion lies beneath the surface and is therefore not exposed to the air. The vaporization of this sub-surface material is therefore inhibited. One object of the present invention is to overcome this deficiency by finding a way to promote volatilization of active decongestant agents.

In view of these and other deficiencies of the prior art, it is one object of the present invention to provide a decongestant for alleviating one or more of the symptoms of nasal congestion, cough, colds or bronchial congestion but which is also comfortable to use, non-greasy and can be easily and quickly removed from the skin when no longer needed.

Another object is to provide an oral and nasal decongestant which readily evolves decongestant vapor that can be inhaled through the mouth or nose but will not spread out on the skin or be accidentally transferred to clothing.

Still another object of the invention is to provide an improved decongestant which readily diffuses into the air but still provides therapeutic effects that are long lasting.

A further object is to provide an improved decongestant and carrier for inhalation therapy which if desired can be structured to also provide analgesic effects through the skin.

These and other more detailed and specific objects of the present invention will be better understood by reference to the following figures and detailed description which illustrate by way of example of but a few of the various forms of the invention within the scope of the appended claims.

SUMMARY OF THE INVENTION

The present invention provides a decongestant, preferably an aromatic, vaporizable decongestant supported on a foraminous carrier composed typically of an open-cell plastic foam, perforated plastic film, cloth or other fibrous material such as nonwoven fabric. The term "foraminous" herein is intended to refer to a substance or medium containing minute openings or perforated by many minute apertures. To form such a product in accordance with the present invention, an inhalable decongestant is placed on surfaces within the interstices and minute apertures or on fibers of which the foraminous carrier is composed. In this way vaporization of the inhalable decongestant is facilitated by providing the potential for greatly increasing its exposed surface area. Thus, distributing the decongestant composition over the large, expanded surface within the foraminous carrier is beneficial in enhancing both the volatilization and evaporation of the decongestant agent. It also helps to prolong the useful life of the product. Once vaporized, the aromatic decongestant is available for natural inhalation through the nose or mouth to help relieve one or more of the symptoms of cough, colds, nasal or chest congestion and related symptoms. The foraminous carrier is preferably provided in the form of a patch or sheet that is bonded to the skin and acts as a supporting base for the active decongestant agent.

The patch defining the carrier is placed on the upper part of the body, typically on the face, neck or chest, in a location where the decongestant is liberated into the air and can be inhaled through the mouth or nose. The patch which serves as a carrier for the decongestant is bonded to the skin either through the provision of an adhesive on the lower surface of the patch or by means of a separate piece of pressure-sensitive adhesive tape or adhesive coating, either surrounding the carrier or applied along the edges of the lower surface of the carrier.

The decongestant can be applied to the foraminous carrier in various ways. For example, by spraying, roll-coating, dipping, knife-coating, or calendering. If desired, the decongestant agent can extend substantially through the entire thickness of the carrier sheet. It is preferred that the entire patch be non-occlusive, i.e. capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch. However, if desired, the foraminous carrier sheet can be provided as an upper layer of the patch which is bonded to a non-porous sheet material such as a sheet of plastic film having a separate layer of pressure-sensitive adhesive on its lower surface for bonding the patch to the skin. In this case, the patch as a whole is occlusive and as such will not allow moisture to escape from the skin.

A variety of well known therapeutic agents that have a decongestant or analgesic action can be employed. Examples include oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline

hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), naphazoline hydrochloride, and other decongestants known in the art. We have found that the turpentine, because of its volatility, appears to help co-evaporate other active decongestant agents. To prepare the patch, the decongestant, i.e. the therapeutic agent, is preferably dispersed in a vehicle to form an ointment that can either be hydrophilic or hydrophobic in nature. A typical hydrophilic vehicle preferably includes a thickener comprising a water-dispersible or water-swellable natural or synthetic polymer. The thickener raises the viscosity to a level that resists spreading and can, if desired, cause the ointment to set-up as an elastic solid. A hydrophilic ointment also contains water and a humectant such as a polyhydric alcohol. Typical hydrophobic vehicles comprise mineral oil or petroleum jelly, or a combination thereof, in which decongestant agents are dispersed or dissolved. Another hydrophobic vehicle comprises a pressure-sensitive adhesive matrix such as a dispersion of natural or synthetic rubber, an oleaginous plasticizer such as mineral oil, and a tackifying resin such as a terpene resin. Other adhesives can be used, such as vinyl emulsion adhesives, acrylic polymeric adhesives, vinyl acetate copolymers or silicone adhesives. Other medical adhesives which can be used will be apparent to those skilled in the art.

When the decongestant agents are mixed with the vehicle, an ointment is produced. The ointment is then stabilized by applying it to the greatly expanded surface area within the minute apertures and interstices between the fibrils, perforations and/or pores of the foraminous carrier. This, together with a thickening agent that can, if desired, be contained in the ointment, gives the ointment sufficient body, support and stability to hold it in place and prevent it from becoming smeared onto fingers, clothing, bed linens or onto other parts of the body where one or more of the decongestant agents could cause irritation, such as nasal mucosa or the eyes. In addition, the foraminous carrier supporting the decongestant enables all of the decongestant material to be easily and quickly removed when no longer needed with little or no residue left on the skin. In addition, by distributing the ointment over the extended surface of the foraminous carrier, more of the decongestant can be exposed to the air. The much greater exposed surface area facilitates evaporation of the decongestant, thus allowing more of the active agents it to be inhaled so as to improve the reduction of nasal or chest congestion and related cold and sinus symptoms.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view showing the invention in use on the chest.

FIG. **2** is a perspective view showing use of the invention between the upper lip and nose.

FIG. **3** is a perspective viewing showing use of the invention on the neck.

FIG. **4** is a perspective view showing the use of the invention on the chin.

FIG. **5** is a greatly enlarged plan view of the invention.

FIG. **6** is a cross-sectional view of the invention taken on line **6**—**6** of FIG. **5**.

FIG. **6A** is a microscopic cross-sectional view of FIG. **6**.

FIG. **7** is a cross-sectional view of another form of carrier.

FIG. **7A** is a microscopic view of FIG. **7** showing the active decongestant distributed on the extended surface of the foraminous carrier.

FIG. **8** is a perspective view of the invention in which medical adhesive tape is used to bond the carrier to the skin, and

FIG. **9** is a perspective view showing the application of adhesive along the edges of decongestant patches embodying the invention.

DETAILED DESCRIPTION OF THE INVENTION

Refer now to the figures in which the same numbers refer to corresponding parts in the several views, and particularly to FIGS. **1** and **5** which illustrate generally rectangular patch **10** that is applied to the upper chest area of a patient. The patch **10** includes an upper flexible foraminous decongestant-supporting carrier sheet **16** and is particularly advantageous for improving symptoms of chest congestion. The patch **10** provides for the evaporation of decongestant indicated diagrammatically at **12** which can then be inhaled by the patient through the nose or mouth. The warming of the patch **10** by the skin after the patch **10** has been applied helps to increase the rate of evaporation of the decongestant vapors **12**. The patch **10** in this case is provided with an underlying layer of medical grade, non-irritating pressure-sensitive adhesive **14** of any suitable type known to those skilled in the art, for example as described in U.S. Pat. Nos. 5,536,263; 4,675,009; 2,498,338; 3,645,835; 4,427,737 and 4,867,150 which are incorporated herein by reference for bonding the patch to the skin. The lower surface of adhesive **14** is protected during shipment and storage by a removable liner sheet **18** (FIG. **5**) that can comprise any suitable commercially available release paper or plastic film. Before use, the liner sheet **18** is removed to expose the lower surface of the pressure-sensitive adhesive **14**. The patch **10** is then applied to the skin and is held in place by the pressure-sensitive adhesive, for example, on the upper chest area of the patient as shown in FIG. **1**.

Overlying the pressure-sensitive adhesive **14** and bonded to it is the foraminous carrier **16** to which an ointment containing a decongestant is applied. If desired, the pressure-sensitive adhesive **14** can have the same composition as the ointment. In such a case, the pressure-sensitive adhesive **14** can also contain a therapeutic medicament comprising a decongestant and/or analgesic agent. It will then be possible for the decongestant or analgesic to be absorbed into the skin to provide a therapeutic effect by absorption into the underlying tissue to achieve localized relief for the symptoms of bronchial congestion. The invention is thus capable of providing a therapeutic effect in two ways simultaneously; namely, by dermal absorption into the skin as well as by inhalation of the decongestant vapors via the mouth or nose. In this way the invention can provide a dual therapeutic action. If the pressure-sensitive adhesive **14** is of a different composition from the ointment, for example an ordinary, non-irritating medical grade rubber-based adhesive, then the patch **10** will have but a single mode of operation; namely, the evolution of the aromatic decongestant vapor **12** for providing inhalation therapy. The patch **10** for use on the chest is typically about 3 inches long by 2 inches wide and has rounded corners. The foraminous carrier sheet typically has a thickness of about 3–8 mils and contains about 0.012 ounces per square inch of the decongestant-containing ointment. The foraminous carrier **16** is typically a flexible sheet of open-cell polyurethane foam, open-cell polyethylene foam, nonwoven fabric or cloth.

Refer now to FIG. **2** which illustrates slightly curved patch **11** applied to the nasolabial area of a user just below

the nose. The patch **10** is particularly advantageous for improving symptoms of nasal congestion or cough by providing for the evaporation of decongestant indicated diagrammatically at **12** into the air, which can then be inhaled by the patient through the nose. The patch **11** has a foraminous upper carrier layer **16** to which the decongestant-containing ointment is applied. The patch **10** also includes an underlying layer of non-irritating medical grade pressure-sensitive adhesive **14** of any suitable type known to those skilled in the art, for example as described above in connection with FIGS. **1** and **5**. The adhesive **14** is protected during shipment and storage by a removable liner sheet (not shown) similar to **18** in FIG. **5** that can comprise any suitable commercially available release paper or plastic film. The pressure-sensitive adhesive **14** bonds the foraminous carrier **16** and the decongestant contained therein in place above the upper lip of the patient just below the nose as shown in FIG. **2**.

The patch **11** for use between the upper lip and nose is typically about 2 inches long by ¾ inches wide and has rounded corners. The foraminous carrier sheet typically has a thickness of about 3–8 mils and contains about 0.012 ounces per square inch of the decongestant-containing ointment. The foraminous carrier **16** can comprise a sheet of open-cell foam plastic, such as a flexible sheet open-cell polyurethane foam, open-cell polyethylene foam, nonwoven fabric or cloth.

Refer now to FIGS. **3** and **4** which illustrate generally rectangular patches **10***a* and **10***b* applied to the neck and chin, respectively. The patches **10***a* and **10***b*, which have the same construction described in connection with FIGS. **1** and **5** but are smaller, are especially useful for improving symptoms of head congestion. Both provide for the evaporation of decongestant into the air as indicated diagrammatically at **12**. The vapor can then be inhaled by the patient through the nose or mouth. The construction of the patches **10***a* and **10***b* is the same as described above. The neck patch **10***a* of FIG. **3**, however, has the decongestant ointment exposed on its lower surface and the ointment contains an adhesive material. Thus, the ointment provides an analgesic effect through dermal absorption, which is useful in relieving the symptoms of cough and itchy throat.

The patch **10***a* or **10***b* for use on the neck or chin is typically about 3 inches long by 2 inches wide and has rounded corners. The overall thickness can be about 5–22 mils and contains about 0.012 ounces per square inch of the decongestant-containing ointment. The foraminous carrier **16** can comprise a sheet of polyurethane foam, cloth or nonwoven fabric. The chin patch is especially advantageous for providing decongestant vapor for oral inhalation.

Refer now to FIGS. **6** and **6A** which illustrate cross-sectional views of the invention as it appears when applied to the skin **15** of a patient after removal of the liner sheet **18**. The foraminous decongestant carrier **16** comprises an upper layer and the pressure-sensitive adhesive **14** comprises a lower layer. The foraminous carrier **16** contains openings or foramina **17** throughout which communicate between the upper and lower surfaces **19** and **21** of the foraminous carrier **16**. This allows moisture from the skin **15** to escape through the patch **10**. Applied to the surfaces lining the apertures and interstices **17** within the foraminous carrier **16** is a quantity of an ointment **22** containing the active aromatic decongestant agent. Support by the carrier **16** makes possible a greatly extended exposed surface due to the multiplicity of minute foramina **17** within the carrier **16**. The increased extended surface area of the ointment within the carrier **16** makes possible much improved volatilization of the aromatic decongestant contained in the ointment, thereby enhancing the liberation of vapor into the air for inhalation therapy through the nose or mouth.

In the patch **10** of FIGS. **6** and **6A**, the pressure-sensitive adhesive layer **14** has the same composition as the ointment **22** which contains both the active decongestant and a suitable adhesive and thickener such as a natural or synthetic polymeric adhesive or gum dispersed in the ointment **22**.

Refer now to FIGS. **7** and **7A** which illustrate a modified form of the invention. In FIG. **7**, a foraminous carrier sheet designated **24** comprises a fibrous sheet formed from non-woven cotton fabric containing microscopic fibers **32** (FIG. **7A**) which are bonded together at their points of contact. A typical foraminous carrier is a flexible sheet about 5 mils thick. Applied within the foramina **35** to the surfaces of the fibers **32** is a decongestant ointment **33**. Bonded to the lower surface of the foraminous carrier **24** by the ointment is a barrier such as a sheet of plastic film, e.g. 2 mil. polyester film **26**. Applied as a coating on the lower surface of the polyester film **26** is a layer of commercially available medical grade non-irritating pressure-sensitive adhesive **28** that bonds the patch **25** to the skin **30**. The foraminous carrier layer **24** comprises a fibrous mass of intersecting fibers **32** (FIG. **7A**) to which the ointment **33** is applied. The microscopic fibers **32** provide an extremely high surface area. This can give the applied ointment **33** containing the active decongestant agent a greatly extended surface area which, as already noted, helps to volatilize the decongestant thus making it more available for inhalation therapy so as to provide greater effectiveness in the relief of the symptoms of cough, colds, nasal congestion or chest congestion. At the same time, the foraminous carrier **24** stabilizes the ointment by holding it in place and keeping the ointment it from spreading onto other parts of the body, the clothing, bed linens, etc. In this embodiment, the ointment **33** contains a thickener that helps the ointment set or gel once applied to the foraminous carrier **24**. For this purpose, we employ a high molecular weight natural or synthetic polymer and optionally a polymeric adhesive as a part of the ointment. Accordingly, the upper portion of the patch **25** can be thought of as a stabilized ointment containing a vaporizable decongestant that is spread over an extended surface of the solid but flexible foraminous carrier **24**.

The form of the invention shown in FIGS. **7** and **7A** has an important advantage since the decongestant contained in the foraminous carrier **24** does not contact the skin. This benefits some people, particularly those with sensitive skin and children, who sometimes complain about the tingling or burning sensation that is noticed when certain decongestants are placed in direct contact with the skin.

Refer now to FIG. **8** which illustrates a decongestant patch **40** in accordance with the invention that is held in place on the skin by means of a sheet of medical grade adhesive tape **42** having an opening **44** cut in its center. The adhesive tape **42** is elongated and has rounded corners. The adhesive tape **42** can be any suitable commercially available medical adhesive tape having an adhesive layer **46** on its lower surface for bonding the patch **40** to the skin and for bonding the adhesive tape **42** to the edge of a flexible foraminous carrier sheet **48** which typically comprises a sheet of plastic foam, fibrous material such as woven or nonwoven plastic or gauze saturated with an aromatic decongestant. The foraminous carrier **48** has side edges **50**, **52** and end edges **54**, **56** which are all bonded in place by the inner edge of the adhesive tape **42** adjacent the opening **44**. It will be understood that the foraminous carrier sheet **48** itself has no adhesive and depends entirely upon the adhe-

sive tape **42** to hold it in place on the skin. The patch **40** can be made in any suitable size and positioned conveniently on the skin wherever desired so that the decongestant vapors when given off can be inhaled through the mouth or nose during normal respiration.

Refer now to FIG. **9** which illustrates the application of adhesive bands on opposed edges of the invention for securing the flexible foraminous carrier to the skin. In FIG. **9**, the foraminous carrier **60** which comprises a strip of fabric passes from right to left in the figure beneath adhesive applicator rolls **62**, **64** which rotate in a given feed direction to apply strips of adhesive **66**, **68** along parallel opposed edges of the carrier **60**. Pressure-sensitive adhesive (not shown) is applied continually to the rolls **62**, **64** to keep the surface of the rolls **62**, **64** coated with adhesive. The foraminous carrier sheet **60** is periodically cut transversely in any suitable manner along separation lines indicated at **70** by a cutter such as a reciprocating blade **72** which severs the carrier sheet **60** transversely at spaced apart locations indicated at **74** to provide finished patches **61** with pressure-sensitive adhesive strips **66**, **68** along opposed edges. The carrier sheet **60** can be of any of the compositions described above. Prior to passing beneath rolls **62**, **64**, a vaporizable decongestant agent **80** of a suitable composition is applied as a spray by means of spray heads **82** to which the decongestant is pumped under pressure through a feed line **84** by means of pump **86** from supply tank **88**. The spray of decongestant material **80** impinges upon the carrier sheet **60** so as to coat the fibers that line the openings or foramina within the foraminous structure of the carrier **60**. If desired, heat can be applied to the sheet **60** to drive off excess moisture and to help thicken the decongestant **80** that has been applied by the spray heads **82**. The decongestant is then supported and stabilized by the foraminous structure of the carrier **60** and, if desired, by a thickening agent contained in the decongestant as described above. The patches **61** are used in the same manner as described above and can be made in any convenient size. In this case the decongestant spray **80** itself contains no adhesive since the patches **61** will be adequately bonded to the skin by means of the pressure-sensitive adhesive strips **66**, **68**.

For various applications, the patches can measure from about 2 inches by 3 inches to about 4 inches by 5 inches, or larger, for application to the chin, neck or chest. When the patch is applied to the nasolabial area just beneath the nose, it can be about 2¾ inches long by ⅜ inches wide with a slight concave upper edge if desired. The patches can be made in other sizes and shapes to fit the portion of the body to which they are applied.

The ointment is prepared by mixing together a vehicle preferably containing a polymeric thickener, either with water or non-polar solvent as the case may be, and a pre-mix containing the active decongestant agent. If the ointment is formed with an aqueous base, a preferred thickener comprises a hydrophilic polymer that is either soluble in water or will swell in contact with water. A humectant such as a polyhydric alcohol is also advantageously employed. The method used for mixing the ointment can be similar to the method used for preparing the medication-containing reservoir described in U.S. Pat. No. 5,536,263 which is incorporated herein by reference.

One preferred form of ointment contains the following: about 0.1% to about 10% camphor; about 0.5% to about 5% menthol; about 0.1% to about 5% eucalyptus oil; about 0.5% to about 10% spirits of turpentine; about 10% to about 60% of a humectant of which a polyhydric alcohol such as glycerin or propylene glycol are examples; and a thickener comprising a natural or synthetic polymeric gum such as karaya or polyacrylamide is provided in the amount of about 5% to about 50%. The active decongestant is preferably prepared as a pre-mix by blending ingredients together in a suitable mixer and then admixing the pre-mix to the ingredients present in the vehicle. All quantities herein are presented as percent by weight unless otherwise specified.

A variety of other natural or synthetic gel-forming polymers can be used as a thickener in place of karaya or polyacrylamide. These include gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, and polyacrylic acid. Optionally, a water dispersible adhesive is provided, such as a carboxylic acid polymer, e.g. Carbotac™ 26222 or 26171 by the B. F. Goodrich Company of Cleveland, Ohio, in the amount of about 0.5% to about 30%. The adhesive, however, can be any suitable non-irritating medical grade adhesive including adhesives such as acrylate emulsion adhesive, acrylic ester copolymer adhesives, vinyl acetate resins, and copolymers of vinyl acetate and dioctyl maleate and the like. Other pressure-sensitive adhesives can be employed such as silicone pressure-sensitive adhesives prepared as described in U.S. Pat. Nos. 3,627,851; 3,772,247; 2,736,721 and 2,814,601 each of which is incorporated herein by reference. Still other pressure-sensitive adhesives that can be used are described in U.S. Pat. No. 2,857,356 which is also incorporated herein by reference. Additional adhesives which can be used are described as adhesives for transdermal delivery devices in U.S. Pat. Nos. 4,951,657; 4,655,767 and 5,232,702 which are all incorporated herein by reference.

One preferred ointment comprises about 6% camphor; about 3% menthol; about 1% eucalyptus oil; about 4% spirits of turpentine; about 44% glycerin; about 1% aloe vera; a thickener comprising about 34% karaya gum; and about 7% of a water-borne latex adhesive such as a carboxylic acid polymeric adhesive, e.g. 2 parts Carbotac™ 26222 and 1 part Carbotac™ 26171. The ointment can be applied to the foraminous carrier either by roll-coating or by knife-coating without dilution or, if applied by spraying or dipping, it can be diluted with an equal amount of water. After being applied, the ointment is then preferably heated, e.g. to between about 120° F. and 150° F. to help drive off excess moisture and to assist in setting the structure of the ointment within the minute foramina of the carrier. This distribution of the decongestant promotes volatilization and evaporation of the active decongestant agent and helps to keep the ointment where it is placed. It also allows it to be cleanly removed from the skin when no longer needed.

The invention has been well received by users because it prevents clothes and fingers from becoming smeared with ointment, while holding the ointment in place where the decongestant vapors will be readily available for inhalation. The invention is also capable of distributing the ointment over the relatively large extended surface of the foraminous carrier to aid in promoting the transfer of the decongestant from the solid state to the vapor state. The invention also enables the decongestant vapor to be reliably evolved over a relatively long period of time, e.g. up to eight or more hours, and was therefore adjudged long-lasting by the average user. In addition, the invention enables the decongestant to act in a dual capacity; namely, both as a vaporous inhalant and also as an analgesic through dermal absorption into the capillaries beneath the skin surface. The decongestant-containing patches have proved effective in the temporary relief of coughs due to colds, minor throat and bronchial irritation, and temporarily suppresses cough occurring with

a cold. When used on the chest, the invention temporarily relieves cough due to colds, minor throat and bronchial irritation and temporarily suppresses cough occurring with a cold. On the chest it can also act as a topical analgesic to relieve minor aches and pains in the chest area via dermal absorption through the skin. The decongestant patches of the present invention are comfortable, non-greasy and easy to apply with little, if any, traces of greasy material being left after removal or transferred to the fingers, clothes or bed linens. The decongestant agents are readily vaporized, and the patch as a whole can be made non-occlusive so as to eliminate the possibility of perspiration becoming trapped beneath the patch. The patches can be made so as to keep the decongestant agent away from the skin to prevent possible irritation. The invention also helps people without cold symptoms to sleep better by making it possible for one to breathe easily through the nose throughout the entire night. The invention is therefore also a sleep aid. Finally, the inhalable decongestants do not appear to interact with other medications that may be taken by the patient.

The finished patches are preferably packaged in envelopes or boxes with instructions to apply them to the upper part of the body; namely, the nasolabial area, the chest, the chin, and the throat.

Many variations of the present invention within the scope of the appended claims will be apparent to those skilled in the art once the principles described herein are understood.

What is claimed is:

1. A skin patch for the relief of the symptoms of cough, colds, nasal congestion or chest congestion, comprising,

symptomatic cold reliever supported upon a non-occlusive flexible foraminous carrier and means operatively associated with the carrier for securing the carrier to the skin surface to enable said symptomatic cold reliever to be available for natural inhalation during respiration through the mouth or nose;

wherein the skin patch is free of a 5-substituted furan methyl ketone.

2. The skin patch of claim **1** wherein the symptomatic cold reliever is an ointment containing an active agent selected from the group consisting of oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), and naphazoline hydrochloride.

3. The skin patch of claim **1** wherein the symptomatic cold reliever is dispersed in an ointment including as a thickener a natural or synthetic gel-forming polymer comprising a member selected from the group consisting of gum karaya, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, and polyacrylic acid.

4. The skin patch of claim **1** wherein the symptomatic cold reliever is dispersed in a vehicle that includes a resin emulsion adhesive.

5. The skin patch of claim **1** wherein said means comprises an adhesive selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, silicone adhesive, natural or synthetic rubber, a petroleum derivative, and a resin.

6. The skin patch of claim **3** wherein the symptomatic cold reliever is dispersed in a vehicle which includes a humectant comprising a polyhydric alcohol.

7. A skin patch, comprising,

a patch body including a flexible foraminous carrier sheet having a multiplicity of minute foramina extending therethrough to provide an extended surface,

an ointment containing a symptomatic cold reliever,

said ointment being distributed upon the extended surface of the foramina within the carrier for supporting and stabilizing the ointment and to promote volatilization and evaporation of the symptomatic cold reliever for inhalation through the nose or mouth to relieve of one or more of the symptoms of cough, cold, nasal congestion, or chest congestion.

8. The skin patch of claim **7** wherein a pressure-sensitive adhesive is exposed on the lower surface of said skin patch for bonding the patch to the skin of a patient.

9. The skin patch of claim **7** wherein said ointment contains a symptomatic cold reliever selected from the group consisting of oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), and naphazoline hydrochloride.

10. The skin patch of claim **7** wherein the ointment includes a thickener comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, and polyacrylic acid.

11. The skin patch of claim **7** wherein the ointment includes a resin emulsion adhesive.

12. The skin patch of claim **7** wherein the ointment includes an emulsion adhesive comprising a member selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, and silicone adhesive.

13. The skin patch of claim **10** wherein the ointment includes a humectant comprising a polyhydric alcohol.

14. A skin patch, comprising,

a flexible laminate for being bonded to the skin of a patient,

said laminate including a vehicle containing a symptomatic cold reliever on at least an upper portion thereof,

a carrier for the vehicle comprising a sheet of flexible foraminous material to support the vehicle, and

a pressure-sensitive adhesive exposed on a lower surface of said patch for bonding the patch to the skin of a patient wherein the skin patch is free of a 5-substituted furan methyl ketone.

15. The skin patch of claim **14** wherein the pressure-sensitive adhesive is a layer of adhesive material applied to a lower surface of said skin patch for bonding the patch to the skin of a patient.

16. The skin patch of claim **14** wherein the symptomatic cold reliever comprises an active agent selected from the group consisting of oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), and naphazoline hydrochloride.

17. The skin patch of claim **14** wherein the symptomatic cold reliever is dispersed in a vehicle including a thickener

comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, polyacrylic acid, a natural or synthetic rubber, a petroleum derivative, and a resin.

18. The skin patch of claim **14** wherein the symptomatic cold reliever is dispersed in a vehicle that includes a resin emulsion adhesive.

19. The skin patch of claim **14** wherein the symptomatic cold reliever is dispersed in a vehicle including an emulsion adhesive comprising a member selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, and silicone adhesive.

20. The skin patch of claim **17** wherein the symptomatic cold reliever is contained in a vehicle that includes a humectant comprising a polyhydric alcohol.

21. A method of reducing or alleviating one or more of the symptoms of cough due to colds, minor throat and bronchial imtation, nasal or chest congestion, comprising,

providing a flexible foraminous carrier,

supporting a symptomatic cold reliever upon the foraminous carrier, and

providing instructions for bonding the foraminous carrier to the skin surface in sufficient proximity to the nose or mouth to enable the symptomatic cold reliever to be available for natural inhalation during respiration through the nose or mouth wherein the skin patch is free of a 5-substained furan methyl ketone.

22. The method of claim **21** wherein the symptomatic cold reliever is an ointment-containing an active agent selected from the group consisting of oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), and naphazoline hydrochloride.

23. The method of claim **21** wherein the symptomatic cold reliever is dispersed in a vehicle which includes a thickener comprising a natural or synthetic polymer.

24. The method of claim **23** wherein the polymer comprises a member selected from the group consisting of karaya gum, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, and polyacrylic acid.

25. The method of claim **21** wherein the foraminous carrier is bonded to the skin by a non-irritating medical grade, pressure-sensitive adhesive connected to the carrier.

26. The method of claim **25** wherein the pressure-sensitive adhesive comprises a member selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, silicone adhesive, natural or synthetic rubber, a petroleum derivative, and a resin.

27. The method of claim **21** wherein the instructions direct one to apply the foraminous carrier to the nasolabial area beneath the nose.

28. The method of claim **21** wherein the instructions direct one to apply the foraminous carrier to the chin.

29. The method of claim **21** wherein the instructions direct one to apply the foraminous carrier to the chest.

30. The method of claim **21** wherein the instructions direct one to apply the foraminous carrier to the throat.

31. The skin patch of claim **7** wherein the skin patch provides a dual therapeutic action including vapor inhalation of the symptomatic cold reliever and dermal absorption of said symptomatic cold reliever into the skin and the underlying tissue.

32. The skin patch of claim **1** wherein the foraminous carrier is a perforated plastic film.

33. The skin patch of claim **31** wherein the symptomatic cold reliever is absorbed into the skin and underlying tissue.

34. The skin patch of claim **31** wherein the ointment contains an analgesic and the symptomatic cold reliever absorbed into the skin and underlying tissue is said analgesic.

35. A skin patch for the relief of the symptoms of cough, colds, nasal congestion or chest congestion, comprising,

a symptomatic cold reliever supported upon a flexible foraminous carrier and means operatively associated with the carrier for securing the carrier to the skin surface to enable the symptomatic cold reliever to be available for natural inhalation during respiration through the mouth or nose;

wherein the symptomatic cold reliever is dispersed in a vehicle that includes a resin emulsion adhesive wherein the skin patch is free of a 5-substituted furan methyl ketone.

36. A skin patch for the relief of the symptoms of cough, colds, nasal congestion or chest congestion, comprising,

a symptomatic cold reliever supported upon a flexible foraminous carrier and means operatively associated with the carrier for securing the carrier to the skin surface to enable the symptomatic cold reliever to be available for natural inhalation during respiration through the mouth or nose;

wherein the means comprises an adhesive selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, silicone adhesive, natural or synthetic rubber, a petroleum derivative, and a resin wherein the skin patch is free of a 5-substituted furan methyl ketone.

37. A skin patch for the relief of the symptoms of cough, colds, nasal congestion or chest congestion, comprising,

a symptomatic cold reliever supported upon a flexible foraminous carrier and means operatively associated with the carrier for securing the carrier to the skin surface to enable the symptomatic cold reliever to be available for natural inhalation during respiration through the mouth or nose;

wherein the symptomatic cold reliever is dispersed in an ointment including as a thickener a natural or synthetic gel-forming polymer comprising a member selected from the group consisting of gum karaya, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, and polyacrylic acid; and

wherein the symptomatic cold reliever is dispersed in a vehicle which includes a humectant comprising a polyhydric alcohol wherein the skin patch is free of a 5-substituted furan methyl ketone.

38. The skin patch of claim **1** wherein the symptomatic cold reliever is a cough suppressant.

39. The skin patch of claim **38** wherein the cough suppressant is a topical antitussive.

40. The skin patch of claim **39** wherein the topical antitussive is camphor or menthol.

41. The skin patch of claim **7** wherein the skin patch provides a therapeutic action including vapor inhalation of the symptomatic cold reliever.

* * * * *

EXHIBIT I

US006844005B2

(12) **United States Patent**
Wahi et al.

(10) **Patent No.: US 6,844,005 B2**
(45) **Date of Patent: Jan. 18, 2005**

(54) **ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH**

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(73) Assignee: **Trutek Corp**, Hillsborough, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 370 days.

(21) Appl. No.: **10/082,978**

(22) Filed: **Feb. 25, 2002**

(65) **Prior Publication Data**

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(51) **Int. Cl.**[7] **A61F 13/02**; A61K 9/14

(52) **U.S. Cl.** **424/434**; 424/443; 424/484; 424/485; 424/486

(58) **Field of Search** 424/434, 443, 424/484, 485, 486, 43

(56) **References Cited**

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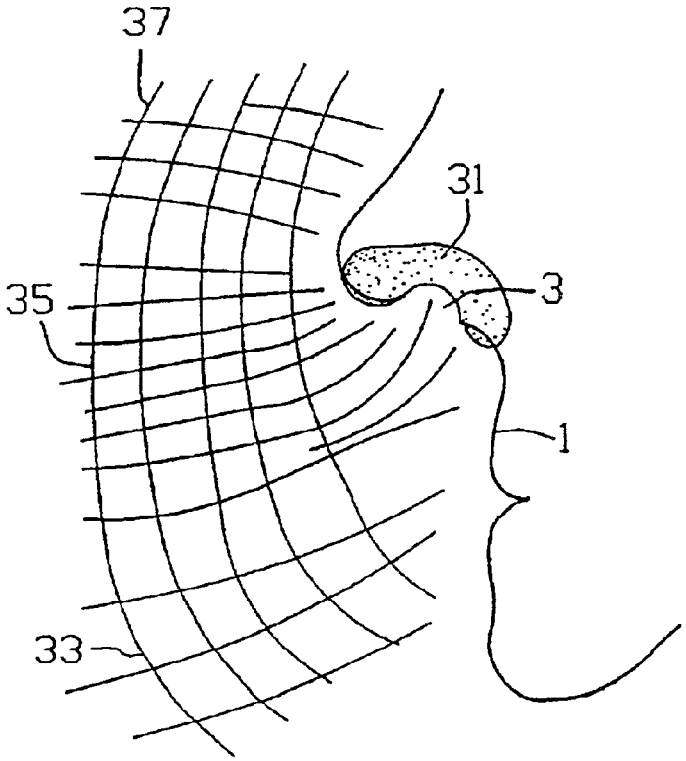
Primary Examiner—Carlos A. Azpuru
(74) *Attorney, Agent, or Firm*—Kenneth P. Glynn, Esq.

(57) **ABSTRACT**

The present invention relates to a nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of a proximate, enhanced electrostatic field. This nasal application product includes: (a) a plurality of masses of one or more electrostatic polymers; and, (b) a topical carrier having the plurality of masses dispersed through a portion thereof. At least one of the electrostatic polymers is a poly (dimethyl diallyl ammonium chloride) polymer and is included in the product in an amount of at least 10% by weight, based on the total weight of the polymers and the topical carrier. The nasal application product may be topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels. The carrier of the nasal application product of the present invention may be selected from the group consisting of dilutents, volatile spray carriers, lotions, solvents, gels and hydrogels. In some embodiments, substrates, e.g., bandage type substrates, with adhesive on one side and the product polymer(s) and carrier on the opposite side, may be employed.

20 Claims, 2 Drawing Sheets



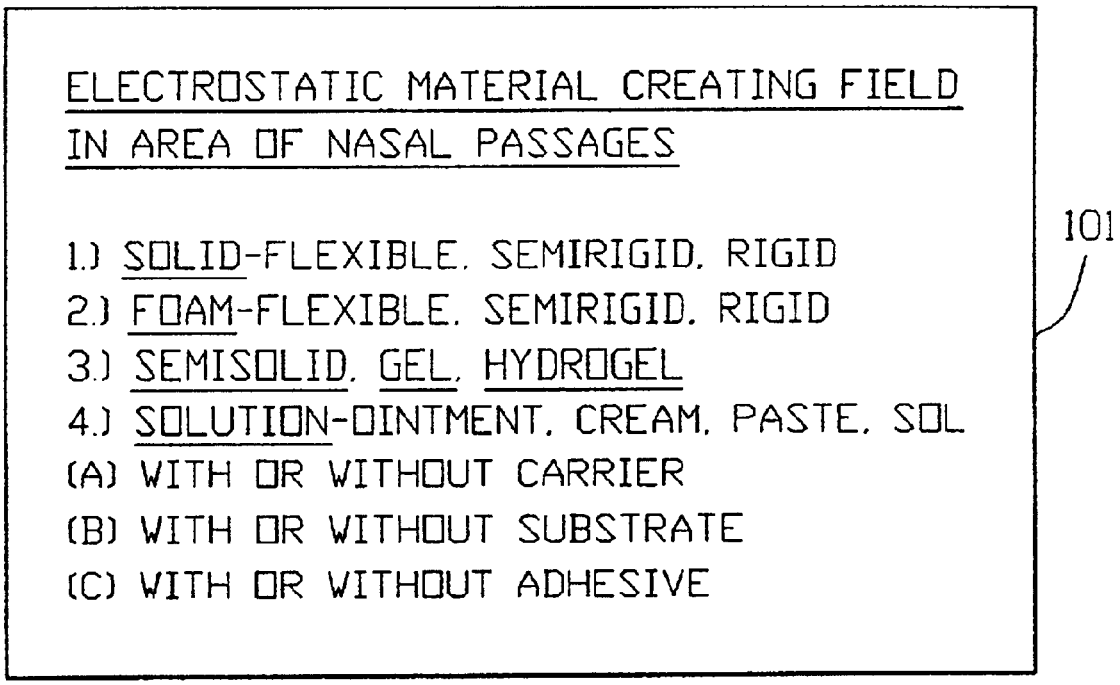

ELECTROSTATIC MATERIAL CREATING FIELD
IN AREA OF NASAL PASSAGES
1.) SOLID-FLEXIBLE, SEMIRIGID, RIGID
2.) FOAM-FLEXIBLE, SEMIRIGID, RIGID
3.) SEMISOLID, GEL, HYDROGEL
4.) SOLUTION-OINTMENT, CREAM, PASTE, SOL
(A) WITH OR WITHOUT CARRIER
(B) WITH OR WITHOUT SUBSTRATE
(C) WITH OR WITHOUT ADHESIVE
101

FIG. 1

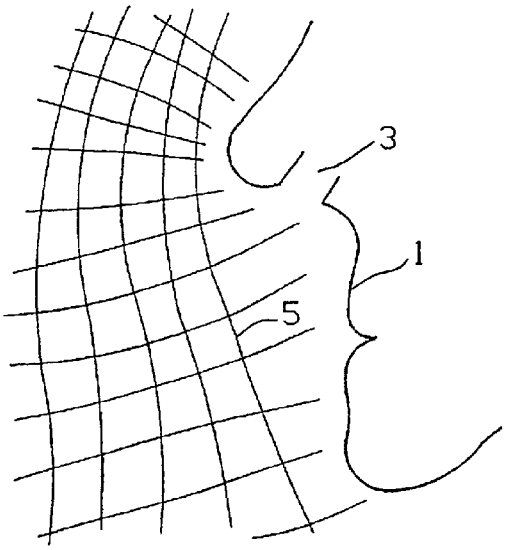


FIG. 2

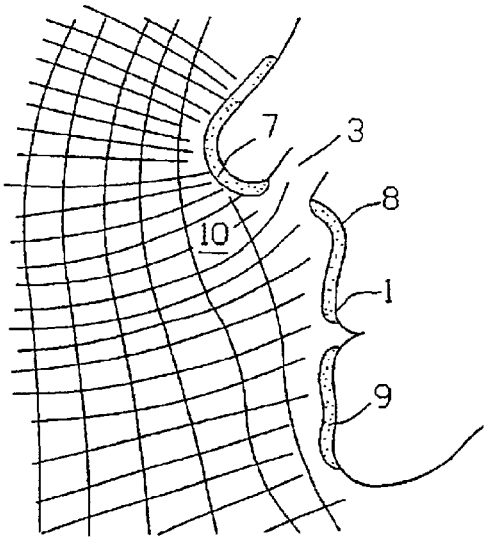


FIG. 3

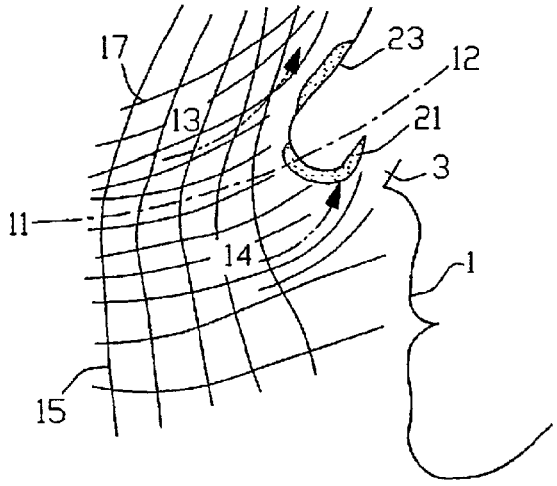


FIG. 4

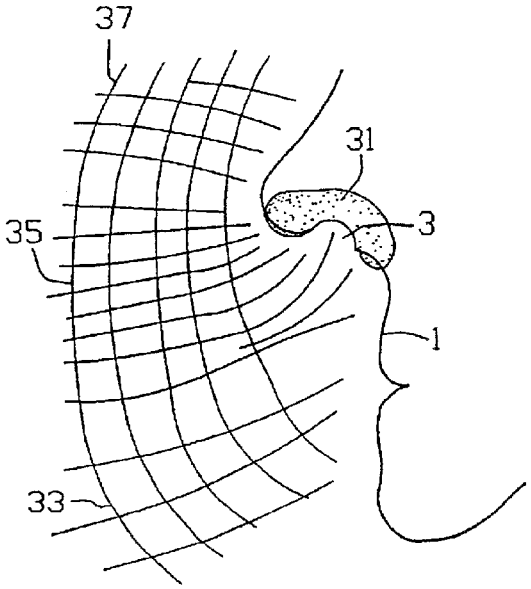


FIG. 5

ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH

REFERENCE TO RELATED CASES

The present invention relates to electrostatically charged topical nasal application products which have been developed and improved since their original development as set forth in two previously issued United States patents. For this reason, the entire specification and claims are incorporated herein in their entirety by reference, as to U.S. Pat. No. 5,468,488, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT AND METHOD" issued to Ashok L. Wahi, inventor, on Nov. 21, 1995, and U.S. Pat. No. 5,674,481, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT" ISSUED TO Ashok L. Wahi on Oct. 7, 1997.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to products for restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage. This prevents or reduces the inflow of airborne contaminants to the nasal passage.

2. Information Disclosure Statement

U.S. Pat. No. 5,468,488 describes a method for restricting the flow of airborne contaminants into a nasal passage. It involves creating an electrostatic field in an area near a human nasal passage. The electrostatic field may either repel or attract airborne contaminants or both. The method involves applying a topical application having a plurality of masses of one or more electrostatic materials, and a carrier having the plurality of masses dispersed therein. The masses have an average cross sectional area of about one square millimeter to about 50,000 square millimeters, and are of sufficient charge to create an electrostatic field which will prevent at least some airborne contaminants from passing into a human nasal passage. The topical application may be in the form of a solution, a semisolid, a solid, a spray solution or a vaporizable solution.

U.S. Pat. No. 5,674,481 describes a product and method for restricting the flow of airborne contaminants into a nasal passage. It involves creating an electrostatic field in an area near a nasal passage. The electrostatic field may either repel or attract airborne contaminants or both. The product may take the form of a plurality of masses of one or more electrostatic materials, the masses have an average cross sectional area of about one square millimeter to about 50,000 square millimeters, the mass being of sufficient charge to create an electrostatic field which will prevent at least some airborne contaminants from passing into a nasal passage. There is also a carrier material with the plurality of masses dispersed therein. The product may be a topical solution, a semi solid, a solid, a spray solution or a vaporizable solution. Alternatively, it may be in a form which includes a substance for the carrier and, in one preferred embodiment, the substrate would be an adhesive material such as a bandage.

The aforesaid references describe various methods and products for restricting airborne contaminant flow to the nasal passage area utilizing the suggested formulae described therein. It has now been discovered that utilization of at least 10% of one specific active electrostatically charged polymer provides significantly increased charge density and efficacy as compared to other electrostatic polymers at lower, the same or higher concentrations than the present invention levels of the poly (dimethyl diallyl ammonium chloride). For this reason, notwithstanding the prior art, the present invention is neither taught nor rendered obvious thereby.

SUMMARY OF THE INVENTION

The present invention relates to a nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of an artificial electrostatic field near the human nose This nasal application product includes: (a) a plurality of masses of one or more electrostatic polymers; and, (b) a topical carrier having the plurality of masses dispersed through a portion thereof. In the present invention, at least one of the electrostatic polymers is a poly (dimethyl diallyl ammonium chloride) polymer and is included in the product in an amount of at least 10% by weight, based on the total weight of the plurality of masses of one or more electrostatic polymers and the topical carrier.

The nasal application product of the present invention may be selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels.

The carrier of the nasal application product of the present invention may be selected from the group consisting of diluents, volatile spray carriers, lotions, solvents, gels and hydrogels. When the carrier is a dilutent, it may be selected from the group consisting of glycols, glycerines, organic surfactants, esters being of unsaturated fatty acids, and mixture thereof. When the carrier is a volatile spray carrier, it may be selected from the group consisting of water, natural oils, glycols, organic surfactants and mixtures thereof. When the carrier is a lotion, it may be selected from the group consisting of polyethylene glycols, natural oils, silicones, homogenizers, and mixtures thereof. When the carrier is a gel, it may be selected from the group consisting of three dimensional polymeric matrices of natural polymers, synthetic polymers, copolymers, and mixtures thereof

In some preferred embodiments of the nasal application product of the present invention, the carrier includes at least one homogenizer and at least one glycol polymer.

In preferred some embodiments of the present invention nasal application product, the carrier includes about 1 to about 5% by weight of a glycol compound and about 60 to 85% by weight of water, based on the total weight of the plurality of masses of one or more electrostatic polymers and the topical carrier. Preferred nasal application product topical carrier formulae include:

(a) about 1% to about 5% by weight of a glycol compound selected from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof;

(b) about 60% to about 85% by weight of water; and,

(c) about 0% to about 2.5% of one or more stearate compounds;

all of the above weight percentages being based on the total weight of the plurality of masses of one or more electrostatic polymers and the topical carrier.

The present invention nasal application products may further include a substrate containing the topical carrier with a plurality of masses of one or more electrostatic polymers dispersed through at least a portion thereof. The substrate may be a flexible substrate, such as a cloth or other woven

material or a synthetic sheet material with an adhesive thereon, e.g., a bandage type of substrate.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention should be more fully understood when the specification herein is taken in conjunction with the drawings appended hereto wherein:

FIG. **1** shows a schematically the product concept of the present invention;

FIG. **2** shows a side partial stylized view of a human illustrating a typical electrostatic field around a human nasal passage;

FIG. **3** shows the same stylized human outline as in FIG. **2** but with an artificially created electrostatic field near a persons nose to restrict the flow of airborne contaminants into the nasal passages;

FIG. **4** shows another alternative present invention embodiment wherein a combination of artificially created electrostatic fields are shown; and,

FIG. **5** shows a mild artificially created electrostatic field.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

The FIGS. **1** through **5** are briefly described above and are identical to the drawings set forth in the two issued patents incorporated by reference stated above. As such, the detailed explanation and description set forth therein is incorporated herein and, thus, not unnecessarily repeated here.

The present invention is based on the surprising and unexpected discovery that a significant increase in electrostatic charge density is achieved with the present invention by use of at least 10% by weight of poly (dimethyl diallyl ammonium chloride). This is contrary to experiences of the inventors wherein increase in the active (electrostatic polymer) after a level achieved at less than 8% or so, did not significantly increase the electrostatic charge density. However, in the case of the present invention, a charge density increase of about 20% to 25% was realized.

The following examples are representative of the present invention:

EXAMPLE #1

Ingredient	% age composition by weight
1. Deionized Water	75.9
2. Potassium Sorbate	0.1
3. Celquat SC 240 C	3.9
4. Polawax 5% in water	4.9
5. Agequat 400	12.9
6. Arlacel 165	1.0
7. Tween 60	0.1
8. Propylene Glycol	1.2
	100.0

EXAMPLE #2

Ingredient	% age composition
1. Deionized water	73.5
2. Celquat SC 240 C	3.8
3. Agequat 400	12.6
4. Polawax 5% in water	9.5
5. Potassium Sorbate	0.1
6. Necon LO	0.5
	100.0

EXAMPLE #3

1. Deionized water	84.9
2. Celquat SC 240 C	4.0
3. Agequat 400	11.0
4. Potassium Sorbate	0.1
	100.0

Generic/Chemical name of the above ingredients are:
Celquat SC 240 C; Quarternary Cellulosic Derivative
Polawax; Fatty Alcohol, Polysorbate Blend
Agequat 400; Poly(Dimethyl Diallyl Ammonium Chloride)
Arlacel 165; Glycerol Monostearate and Polyethylene Stearate
Necon LO; A surfactant
Tween 60; Polysorbate
Propylene Glycol; 1,2-Propane Diol

Celquat SC 240C is a polyquatermary animonium cellulose manufac ed by National Starch and Chemical Company (New Jersey). Necon LO is dimethy lauramine oleate manufactured by Aizo Inc. (A New Jersey Corporation). Arlacel 165 is a 50/50 mixture of glyscerol monosterate and polyoxyethylene stearate manufactured by Uniqema Corp.

Brief Process of Formulation:

In all of the above Examples, the ingredients are added one by one, at room temperature, in the order listed to water, while stirring. No new ingredient is added until the one added before was dispersed completely. Polawax and Arlacel were dispersed by warming the mixture, to 60 degrees C., over a water bath. After all the ingredients were added, the contents were mixed well for uniformity, let cool to room temperature and bottled.

EXAMPLE #4

Ingredient	Weight (Kg/15 Kg)	% w/w
1. Polawax (5% dispersion)	0.7500	5.00
2. Propylene Glycol	0.3000	2.00
3. Celquat SC-240C	0.6000	4.00
4. Agequat 400	1.6500	11.00
5. Methylparaben	0.0300	0.20
6. Propylparaben	0.0150	0.10
7. Tetrasodium Edetate	0.0075	0.05
8. Arlacel 165	0.1500	1.00
9. Tween 60	0.0150	0.10
10. Gerinall-II	0.0450	0.30
11. Water	11.4375	76.25
TOTAL	15.0000	100.00

Prodedure:

In a suitable container prepare a 5% dispersion of Polawax in water by mixing 37.5 g in 750 g of water previously heated at 70 plus of minus 5 degrees C. (Step A)

In a tared stainless steel container with 10 Kg of water previously heated at 70 plus of minus 5 degree C. and stirred mechanically, add Celquat SC-240C gradually, directly into the vortex. Make sure no clumps are formed. As the dispersion thickens, increase the speed of the mixer enough to maintain the movement of the surface and the bulk of the dispersion. Allow mixing for one to one and a half hour to get a clear, uniform, transparent dispersion at 70 degrees C. Add sequentially Tetrasodium Edetate, Arlacel 165, Tween 60 and Agequat 400 with mixing, making sure that each ingredient is completely dissolved or dispersed before adding the next one. (Step B)

Add dispersion in step A to the dispersion in step B with continued mixing. Allow the mixture to cool down gradually to about 50 degrees C. (Step C)

In a suitable container dissolve Methylparaben, Propylparaben and Germall-II in Propylene Glycol and heat. (Step D)

When the temperature of the mixture from step D reaches 50 degrees C. add solution in step C with continued mixing. (Step E)

Dilute the combined mixture from step E to 15.0 Kg by adding Water previously heated at 50 degrees C. and continue mixing.

Allow the product to cool to 30 degrees C. to form a gel.

Transfer the bulk gel to suitable polyethylene lined containers.

Comparative tests of electrostatic charge density revealed an increase of 20% to 25% as compared to prior art formulations and as compared to other formulations having over 10% electrostatic polymer using actives other than poly (dimethyl diallyl ammonium chloride).

Obviously, numerous modifications and variations of the present invention are possible in light of the above suggestions. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

What is claimed is:

1. A nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of an artificial electrostatic field near the human nose, wherein the nasal application product consists essentially of:

(a) a plurality of masses of one or more electrostatic polymers; and,

(b) a topical carrier having said plurality of masses dispersed through a portion thereof;

wherein at least one of said one or more electrostatic polymers is a poly (dimethyl diallyl ammonium chloride) polymer and is included in said product in an amount of at least 10% by weight, based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

2. The nasal application product of claim **1** wherein said product is selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions.

3. The nasal application product of claim **1** wherein said product is selected from the group consisting of ointments, pastes, creams and gels.

4. The nasal application product of claim **1** wherein said carrier is selected from the group consisting of diluents, volatile spray carriers, lotions, solvents, gels and hydrogels.

5. The nasal application product of claim **1** wherein said carrier is a dilutent selected from the group consisting of alcohols, glycerines, organic surfactants, esters being of unsaturated fatty acids, and mixture thereof.

6. The nasal application product of claim **4** wherein said carrier is a volatile spray carrier selected from the group consisting of water, natural oils, glycols, organic surfactants and mixtures thereof.

7. The nasal application product of claim **4** wherein said carrier is a lotion selected from the group consisting of polyethylene glycols, natural oils, silicones, homogenizers, and mixtures thereof.

8. The nasal application product of claim **4** wherein said carrier is a gel selected from the group consisting of three dimensional polymeric matrices of natural polymers, synthetic polymers, copolymers, and mixtures thereof.

9. The nasal application product of claim **1** wherein said carrier includes at least one honogenizer and at least one glycol polymer.

10. The nasal application product of claim **9** wherein said carrier includes about 1 to about 5% by weight of a glycol compound and about 60 to 85% by weight of water, based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

11. The nasal application product of claim **10** wherein said topical carrier includes:

(a.) about 1% to about 5% by weight of a glycol compound selected from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof;

(b.) about 60% to about 85% by weight of water; and,

(c.) about 0% to about 2.5% of one or more stearate compounds;

all of the above weight percentages being based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

12. The nasal application product of claim **1** wherein said product further includes a substrate containing said carrier with said plurality of masses of one or more electrostatic polymers dispersed through a portion thereof.

13. The nasal application product of claim **11** wherein said substrate is a flexible substrate having an adhesive thereof.

14. The nasal application product of claim **11** wherein said substrate is a bandage.

15. The nasal application product of claim **12** wherein the nasal application product of claim **1** wherein said carrier includes at least one homogenizer and at least one glycol polymer.

16. The nasal application product of claim **15** wherein the nasal application product of claim **9** wherein said carrier includes about 1 to about 5% by weight of a glycol compound and about 60 to 85% by weight of water, based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

17. The nasal application product of claim **16** wherein said topical carrier includes:

a. about 1% to about 5% by weight of a glycol compound selected from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof;

b. about 60% to about 85% by weight of water; and,

c. about 0% to about 2.5% of one or more stearate compounds;

all of the above weight percentages being based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

18. The nasal application product of claim **13** wherein said carrier includes at least one homogenizer and at least one glycol polymer.

19. The nasal application product of claim **18** wherein said carrier includes about 60 to 85% by weight of water, based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

20. The nasal application product of claim **19** wherein said topical carrier includes:

a. about 1% to about 5% by weight of a glycol compound selected from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof;

b. about 60% to about 85% by weight of water; and,

c. about 0% to about 2.5% of one or more stearate compounds;

all of the above weight percentages being based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

* * * * *

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

CERTIFICATE OF SERVICE

Undersigned hereby states that on August 15, 2022, the attorneys for Plaintiff caused the foregoing document to be served upon all counsel of record, via electronic service.

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Attorney for the Plaintiff

EXHIBIT 7

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff/Counter-Defendant,
v.
BLUEWILLOW BIOLOGICS, INC.
Defendant/Counter-Plaintiff,
ROBIN ROE 1 through 10 (fictitious names); ABC CORPORATION 1 through 10 (fictitious names),
Defendants.

Case No.: 2:21-cv-10312

Deposition of EDWARD A. LEMMO, PH.D.
Conducted Remotely
Monday, October 24, 2022
10:00 a.m.

Job No.: 468438
Pages: 1-283
Reported by: Matthew Goldstein, RMR, CRR

Deposition of EDWARD LEMMO, PH.D., conducted remotely:

Pursuant to Notice, before Matthew Goldstein, RMR, CRR, Notary Public in and for the State of Maryland.

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFF, TRUTEK CORP.:
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4 Lenape Lane
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ON BEHALF OF THE DEFENDANT, BLUEWILLOW BIOLOGICS, INC.:
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ALSO PRESENT:
JENNIFER PODIS - REMOTE TECHNICIAN
JOHN PARKMAN - VIDEOGRAPHER
ASHOK WAHI

C O N T E N T S

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(Continued)

E X H I B I T S

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No. 2:21-cv-10312.

Today's date is Monday, October 24th, 2022. The time on the video monitor is now 10 a.m. Eastern Time.

The remote videographer today is John Parkman representing Planet Depos.

All parties to this video deposition are attending remotely.

Would counsel please voice identify themselves and state whom they represent.

MR. KREMEN: Stanley Kremen for the plaintiff.

MS. PETERSON: And Liane Peterson from Foley & Lardner LLP, on behalf of the plaintiff, BlueWillow Biologics -- or sorry, on behalf of the defendant, BlueWillow Biologics.

THE VIDEOGRAPHER: The court reporter today is Matthew Goldstein also representing Planet Depos.

Would the reporter please swear in the witness.

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THE REMOTE TECHNICIAN: Thank you to everyone for attending this proceeding remotely, which we anticipate will run smoothly.

Please remember to speak slowly. Do your best not to talk over one another. Please be aware that we are recording this proceeding for backup purposes.

Any off-the-record discussions should be had away from the computer. Please remember to mute your mic for those conversations.

Please have your video enabled to help the reporter identify who is speaking. If you're unable to connect with video and connecting via phone, please identify yourself each time before speaking.

I apologize in advance for any technical-related interruptions. Thank you.

THE VIDEOGRAPHER: All right. Just a moment, please, and I'll get us on the record.

Here begins media No. 1 in the videotaped deposition of Dr. Edward A. Lemmo in the matter of Trutek Corporation versus BlueWillow Biologics Incorporated, et al., in the United States District Court Eastern District of Michigan, Southern Division, Case

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P R O C E E D I N G S

Whereupon,

EDWARD LEMMO, PH.D.,

being first duly sworn or affirmed to testify to the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR THE DEFENDANT

BY MS. PETERSON:

Q. Good morning. Can you please state your full name and address for the record?

A. Yes. My name is Edward, middle name is Anthony, last name is Lemmo. And my home address is 60 Gilroy Street, Staten Island, New York 10309.

Q. And just to introduce myself, my name is Liane Peterson. I'm with the law firm of Foley & Lardner. And I am counsel representing the defendant, BlueWillow Biologics, in this case. So I'll be asking the questions today.

Can I ask you, Dr. Lemmo, where are you located today?

A. I'm located in my home.

Q. Is there anybody else in the room with you?

A. No.

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Q. And, Dr. Lemmo, have you had your deposition taken before?
A. I've never given a deposition.
Q. And I assume that would be no deposition in an expert capacity; correct?
A. That's correct.
Q. And you've never had your deposition taken in any other capacity, like in your personal capacity?
A. No, unless you consider something like traffic court.
Q. Okay. Well, let me just run through a few ground rules just to kind of familiarize you with the process.
So I'll be asking you a series of questions throughout the day. I would ask that you wait until I finish with my question before responding. And, of course, I'll try to do the same when you're speaking. I'll try to wait to ask my next question until when you're done.
Is that okay?
A. That's fine. Thank you.
Q. And, of course, it's really important that we try not to speak over each other because that will help Matthew, our court reporter, take

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down a clean and accurate record of the deposition today. Okay?
A. Thank you. Yes.
Q. I would also ask that you provide verbal responses and answers to my questions rather than shaking your head or nodding or saying "uh-huh."
Is that fine?
A. That's fine.
Q. Okay. And let me know at any point if you don't understand my question. I can rephrase it if you need me to. Otherwise, if you don't ask me for clarification, I'll assume that you understand the question. Okay?
A. Yes. Thank you.
Q. And, Dr. Lemmo, are you aware of any reason why you would be unable to provide complete and truthful testimony during this deposition today?
A. No.
Q. Okay. Now, one other kind of housekeeping note, so Jennifer, our technician, will be displaying the exhibits up on the screen, and she can move through those if we need to look at any particular sections. And at the same time, when the exhibit is marked, she's going to put a

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copy of the exhibit in the chat -- in the chat room. And so you can directly open up the document from there. Once we use a document, you can open it from the chat, and then that way you can look at it separately on your own, as well. Okay?
A. Okay. Okay.
Q. And that will be available to everybody.
MR. KREMEN: Can I ask a question, Liane? We last time -- at the last deposition we agreed that we would have universal numbering of exhibits. So that -- Exhibits 1 through 11 have already been numbered.
Is that okay with you?
MS. PETERSON: Yeah, so we'll start with any new exhibits today with 12. Yep, that's the plan.
MR. KREMEN: Sorry for interrupting.
MS. PETERSON: Okay. Let's go ahead and pull up the first exhibit. And this is going to be the deposition notice of Dr. Lemmo. And we'll mark that as Exhibit 12.
(Lemmo Deposition Exhibit 12 was marked for identification and attached to the transcript.)

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BY MS. PETERSON:
Q. Dr. Lemmo, have you seen Exhibit 12 before?
A. No, I have not.
Q. But you understand that you are appearing today pursuant to this deposition notice that's been marked as Exhibit 12?
A. Yes.
MS. PETERSON: We can take that down.
BY MS. PETERSON:
Q. Dr. Lemmo, have you been retained as an expert, either in a testifying or consulting capacity, for any matter other than this matter in the past four years?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Yes.
BY MS. PETERSON:
Q. And how many matters?
A. In a -- as a consultant -- can you just repeat the question?
Q. Have you been retained as an expert -- I'll break it down.
Have you been retained as a testifying expert in any other matters in the past

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four years, apart from this matter involving Trutek?
A. No.
Q. Have you been retained as a consulting expert to provide consulting expert analysis in connection with any litigation matter in the past four years?
A. Yes.
Q. How many times?
A. One time.
Q. And who were the parties involved?
A. Trutek and Matrixx Initiatives.
Q. And in connection with that prior matter for Trutek involving Matrixx, did you prepare any expert reports?
A. Yes.
Q. How many?
A. I believe it was three. I may be wrong.
Q. And do you recall the general subject matter of those three reports?
A. Not offhand. I spoke about the infringement of the patent, the patent by Trutek, by Matrixx representing the Zicam product line.
Q. And did all three reports that you prepared in connection with the Trutek Matrixx

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matter involving infringement of the Zicam product?
A. It was the Zicam product infringing on the technology of Trutek.
Q. Okay. But did all three of the reports that you prepared, did they all relate to those issues of infringement, or did they cover other issues, as well?
A. I don't remember.
Q. And did you -- have you ever prepared a declaration or some other type of sworn statement for any prior litigation proceeding involving Trutek?
A. No.
Q. And what about apart from litigation, have you prepared or signed any declarations or expert reports in connection with any other contested proceedings such as an IPR involving Trutek?
A. Yes.
Q. How many times?
A. I believe once or twice.
Q. And were those IPR proceedings or something else?
A. IPR proceedings.

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Q. And do you know what patent was the subject of those IPR proceedings?
A. I'm sorry, can you explain that?
Q. Well, you understand that an IPR proceeding challenges the validity of a patent at the United States Patent and Trademark Office; correct?
A. Yes.
Q. Do you know what patents were being challenged in those IPR proceedings for which you prepared declarations?
A. I believe it was the Trutek '802 patent.
Q. And have you ever been retained by any other entity or any other party to provide any declaration or expert testimony in any other IPR proceeding?
A. No.
Q. What about a PGR proceeding?
A. I don't know what a PGR proceeding is.
Q. Okay. What about a reexamination, are you familiar with that?
A. No.
Q. So you haven't prepared any declarations or provided any testimony in connection with a reexamination either?

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A. No.
MR. KREMEN: Objection to the form of the question.
BY MS. PETERSON:
Q. And to the best of your knowledge, are you -- actually, let me back up.
Going back to those IPR proceedings for which you were retained by Trutek, how many declarations did you prepare?
A. Again, I believe it was either one or two.
Q. Okay. To the best of your knowledge, are you aware if your proposed testimony or opinions has ever been challenged or excluded by a court or the patent office?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Can you rephrase that for me?
BY MS. PETERSON:
Q. Just if you even know, to the best of your knowledge, has your proposed opinions contained in any of your prior reports or declarations, has it ever been challenged in terms of whether it's admissible?

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A. Not to my knowledge.
Q. And have you -- apart from the work that you've done in connection with the prior Trutek matter involving Matrixx and the current Trutek matter involving BlueWillow, have you ever provided any consulting services in connection with any nasal antiseptic products?
A. No.
Q. And so I would also assume that you haven't prepared any reports or any declarations in connection with any analysis of any nasal antiseptic products for purposes of acting as a testifying expert either?
A. Correct.
Q. And have you ever provided any consulting services for any other company apart from these two matters with respect to compositions intended to be applied to the nasal passages for reducing the risk of infection by either bacteria or viruses?
A. No.
MR. KREMEN: Objection to the form of the question.
BY MS. PETERSON:
Q. And I assume you haven't been retained

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as an expert to testify on any such matters either; is that correct?
A. That's correct.
Q. Have you ever been retained by Trutek to provide any expert or consulting services on any other matters beyond this BlueWillow and the prior Matrixx matter?
A. No.
Q. Have you ever been retained by Trutek's counsel, Mr. Stanley Kremen, previously on any other matter?
A. No.
Q. And have you ever been retained by Trutek's other attorney, Keith Altman of the Altman law firm, on any other matter?
A. No.
Q. And what about Amirali Haidri -- I don't know if I said that name correct -- have you ever been retained by him or his firm to provide any expert or consulting services?
A. No.
Q. Dr. Lemmo, when were you retained by Trutek for this matter?
A. I believe it was sometime in 2021.
Q. And do you recall when you were retained

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by Trutek for the Matrixx matter?
A. I believe that was in 2019.
Q. And so prior to your retention in 2019, as I understand it, you had no prior contact or any involvement with Trutek; is that correct?
A. That's correct.
Q. Or any employees of Trutek?
A. That's correct.
Q. Or any of the lawyers representing Trutek?
A. That's correct.
Q. And who were you retained by for this matter?
A. Mr. Kremen.
Q. Okay. Do you intend to testify at the trial in this case?
A. If necessary --
Q. And what about --
A. -- yes.
Q. What about the Markman hearing, do you intend to testify there?
A. If necessary, yes.
Q. Have you been asked to?
A. No.
Q. And will you be compensated for

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testifying at trial?
A. I believe so, yes.
Q. And what is your hourly rate that you're charging Trutek for this matter?
A. $250 per hour.
Q. And is that the same rate that you charge for providing testimony, whether by deposition or at trial?
A. Yes.
Q. Approximately how many hours have you accrued to date working on this matter?
A. From the beginning you're referring to, from when I was first retained in 2021?
Q. Yes.
A. It's hard for me to say. I could give you an estimate, if that's okay.
Q. Yeah, give me an estimate.
A. I would say perhaps 60 hours.
Q. And that's your best estimate sitting here today?
A. That's my best estimate. It's difficult without information in front of me for how many times I either had to do reviews of material or had conversation with the attorney or any matter related to this.

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Q. Do you keep records of how much time you spend working on this matter?
A. Yes.
Q. And do you send invoices to Mr. Kremen?
A. I send invoices directly to Trutek.
Q. Okay. And whose attention are those sent to?
A. They're sent to Ashok Wahi, and I copy Mr. Kremen.
Q. Okay.
Okay. So just generally speaking, I don't want to know necessarily the subject of any conversations, but I would like to know the names of the people that you have spoken with in connection with your work on this matter involving BlueWillow.
A. Conversations include Stan Kremen, Ashok Wahi, Alexi Ermakov, and Shane Burns.
Q. Okay. Now, let's start with Alex Ermakov. How many times have you spoken with him?
A. One time.
Q. When was that?
A. It was in October. I believe it was October 14th.
Q. Of what year?

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A. 2022.
Q. Okay. So a little over a week ago?
A. About two weeks ago, yes.
Q. Okay. And that's the only conversation you've had with Dr. Ermakov.
A. Yes.
Q. What was the subject matter of your conversation?
A. To get clarification and also to see the design of his study. I met him at his laboratory.
Q. And where is his laboratory located?
A. Rutgers University.
Q. And what were you seeking clarification on?
A. I wanted clarification on how he conducted the measurement for surface charge.
Q. Okay. And then you also mentioned speaking to him or to see the design of his study. What did that involve?
A. To visit his laboratory and see the equipment itself.
Q. So you viewed the equipment that he used?
A. Yes.
Q. Did you watch it in operation?

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A. Yes.
Q. Did you watch the actual study that Dr. Ermakov conducted?
A. No.
Q. Did he replicate that study for you when you visited him on October 14th, 2022?
A. He did not replicate it.
Q. And then just to confirm, I would expect that since the only time you spoke to Dr. Ermakov or met with him in person was about ten days ago, would it be fair to say that you did not speak with him prior to submitting your opening report or your reply report in this matter?
A. Yes.
Q. And you did not view the equipment that he used in this study prior to preparing any of your expert reports either; correct?
A. Only on the report diagram where the equipment is shown as a pictorial.
Q. Okay. So apart from what was contained within Dr. Ermakov's report, you did not view the equipment or visit his laboratory prior to preparing any of your expert reports?
A. Correct.
Q. Okay. And what about Mr. Burns, how

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many times did you speak with him?
A. One time.
Q. And was that also an in-person visit?
A. Yes.
Q. And where is he located?
A. Pennsylvania.
Q. And where did you visit him specifically?
A. At his laboratory.
Q. And when was that visit?
A. About a week later. So it would be -- I'd have to look, but I think it was the 21st.
Q. And apart from that meeting with Mr. Burns on October 21st -- actually, let me confirm. That's October 21st, 2022?
A. 2022, correct.
Q. Okay. So apart from that one meeting with Dr. Burns on October 21st, 2022, is it correct that you had no other conversations with Mr. Burns at any time regarding the subject matter of his testing?
A. That's correct.
Q. Did you ever meet with Dr. Ermakov or Mr. Burns to discuss the testing that they conducted on the Matrixx products?

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A. No.
Q. And no conversations, telephone or Zoom, with Dr. Ermakov or Mr. Burns to discuss the testing conducted on the Matrixx products?
A. No.
Q. And what was the reason why you met with Mr. Burns on October 21st, 2022?
A. To, again, view his equipment, how he conducted the test.
Q. And prior to your visit on October 21st, 2022, you had not viewed the equipment or personally overseen how he conducted the test?
A. Correct.
Q. And when you visited him on October 21st, 2022, did he repeat or replicate the testing that he did?
A. He simply gave a demonstration of the equipment, but did not repeat the test.
Q. And what equipment did he demonstrate?
A. He used a NanoCoulomb Meter, and he used a Faraday cup.
Q. And was he actually testing anything, or did he just show how the products operate?
A. He just showed how the product operates.
Q. So he didn't --

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A. Or how the -- I'm sorry, how the equipment operates.
Q. Okay. So he didn't take a particular substrate and apply something to it and conduct any measurements?
A. No.
Q. Okay. And so I will also assume that he didn't demonstrate anything to you about how he used the pig's skin in his experiments?
A. No.
Q. And why -- well, did you ask to set up these meetings with Dr. Burns -- or sorry, Mr. Burns or Dr. Ermakov, or was it counsel's suggestion?
A. I think it was a combination of getting clarification to see what actually transpired in the laboratory. So collaboration with both counsel as well as myself.
Q. And why did you feel it was necessary to get that clarification?
A. When you look at the reports of both Dr. Ermakov and Mr. Burns, there are pictures and descriptive terminology, but since I am not a specialist in that particular area, I wanted to see the equipment and how the equipment operates

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just to feel more comfortable that my understanding of what testing they did was accurate.
Q. And apart from the meetings with Mr. Burns and Dr. Ermakov in October of 2022, what else did you do to confirm your understanding of the accuracy of their testing?
A. The only other items was to review in the literature how surface charge is measured.
Q. So just to make sure I understand. Apart from your meetings with Dr. Burns -- Mr. Burns and Dr. Ermakov to view the equipment that was used and a literature search concerning how surface charge is measured, you did not do anything else to confirm your understanding of the accuracy of the Burns and Ermakov testing; correct?
A. That's correct.
Q. Now, you also mentioned that you're not a specialist in that type of testing; is that correct?
A. Yes.
Q. And so I assume that's why you didn't do the testing yourself?
A. Yes.

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Q. Have you ever conducted that type of testing of the surface charge measurements?
A. No.
Q. Have you ever performed any testing to determine the conductivity of materials on a substrate?
A. No.
Q. Okay. Going backwards a little bit now. You also mentioned that you spoke with -- in connection with your work on this matter, that you also spoke with Mr. Kremen and Mr. Wahi; correct?
A. Correct.
Q. Do you recall speaking with anybody else other than those four individuals in connection with your work on this matter?
A. No.
Q. Okay. And how many times did you speak with Mr. Wahi?
A. In person, two times.
Q. Okay. And how about either by telephone or by video?
A. Maybe eight times.
Q. That's a lot of meetings. I'm not going to ask you to remember the details of every single one of them, but do you recall when the first

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meeting was?
A. With Mr. Wahi?
Q. Yeah.
A. Regarding this matter, he contacted me, I believe it was November of 2021. I may be wrong, but I believe it was November.
Q. And was that before or after you had been retained for the matter?
A. Yes.
Q. And what was the subject matter of that discussion?
A. He approached me to utilize me as a consultant expert to evaluate the matter.
Q. And what matter are you referring to?
A. The matter of Trutek versus BlueWillow.
Q. Okay. Did Mr. Wahi ever contact you or ask you to work as a consultant on any matter other than the ones directed to Matrixx and BlueWillow?
A. No.
Q. Okay. And when was the most recent meeting that you had with Mr. Wahi?
A. By telephone.
Q. And when was that?
A. By telephone, it was Friday the 21st.

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Q. And what was the purpose for that meeting?
A. He asked me if I needed any further clarification on the matter.
Q. And did you?
A. No.
Q. Okay. And when were the two in-person meetings that you had with Mr. Wahi?
A. Well, one they were several weeks back to discuss, you know, at his facility just to, again, get clarification and then on another occasion to talk about the tests of Dr. Ermakov and Mr. Burns.
Q. Okay. And what clarification were you seeking in that first meeting?
A. The understanding of the claims that are utilized in the '802 patent by Mr. Wahi.
Q. And that meeting you said was several weeks ago?
A. Several weeks ago, yes.
Q. So sometime in September or October of 2022?
A. Probably. I'm not certain to the exact date again. I'd have to look that up.
Q. Okay. But it would have been after you

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prepared your expert reports in this matter?
A. Yes.
Q. Okay. And I assume the same is true about the second in-person meeting to talk about the Ermakov and Burns test, was that also within the last couple of weeks?
A. Yes.
Q. And what did you discuss with Mr. Wahi concerning the Ermakov and Burns test?
A. The question of measurement being surface charge versus the statement that Dr. Amiji raised regarding conductivity.
Q. Okay. And what did you discuss?
A. Simply to have a better understanding of the measurement technique, whether it was, in fact, a measurement of surface charge, or was it conductivity that was measured.
Q. And would it be fair to say that you had that conversation because you were unsure of that yourself based on your own experience?
A. Just to get reinforcement of the subject.
Q. And did that conversation change your understanding in any way --
A. No.

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Q. -- that you had prior --
A. No.
Q. So if you already had an understanding, why did you feel it necessary to confirm it?
A. Again, the question of -- that I like to see things and also to ask questions of the people involved so that my understanding of the situation is exactly the same as how they see it.
Q. And did you have any conversations with Mr. Wahi prior to preparing your expert reports?
A. No.
Q. So all of your meetings with Mr. Wahi, whether by phone or video or in person, have been sometime in just the last month or two of 2022; is that correct?
A. Correct.
Q. But that would be other than the first meeting --
A. Yes.
Q. -- where Mr. Wahi contacted you about the matter?
A. Yes. I'm sorry I interrupted you. Yes, that's correct.
Q. Okay. So as best you can remember, the next meeting that you had with Mr. Wahi would have

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been after you prepared your expert reports?
A. Yes.
Q. Okay. What about your work on the Matrixx matter, did you ever have any conversations with Mr. Wahi in connection with that matter?
A. No.
Q. Okay. So apart from Mr. Kremen, Mr. Wahi, Mr. Burns, and Dr. Ermakov, is there anybody else that you had any discussions with, whether by phone or video or in person, regarding the subject matter of this dispute?
A. No.
Q. Did you speak with anybody else at Trutek?
A. Well, not regarding the matter. There are people there, and so I did greet them, if that's what you're referring to. No. But no. The answer is no.
Q. No, I'm talking -- yeah, I'm talking about substantive conversations about the issues raised in the matter.
A. No.
Q. Okay. Have you had any conversations with Mr. Haidri regarding this matter?

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A. No.
Q. And did anyone else assist you in formulating your opinions provided in this matter?
A. No.
Q. I should also ask -- you mentioned the expert that's retained by my client, BlueWillow, and that's Dr. Amiji. Do you know him?
A. No, I do not.
Q. Dr. Lemmo, just very generally speaking, in your understanding, what was the nature of your assignment for this matter?
A. The nature of my assignment was to provide expertise to demonstrate that the BlueWillow product was infringing on the patent of Trutek, the '802 patent, in the claims that NanoBio makes and is commercially available.
Q. I'm sorry, what do you mean by "the claims that NanoBio makes"?
A. The product that's marketed by BlueWillow as NanoBio Protect provides claims in their advertising and on their packaging that resemble the Trutek product that is known as NasalGuard.
Q. Okay. So you're referring to the statements from BlueWillow's website that are

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referenced throughout your report?
A. Yes.
Q. Okay. And then with respect to commercial availability, you understand that NanoBio Protect is no longer being sold?
A. Yes.
Q. Okay. So you also mentioned a Trutek product that's known as NasalGuard; correct?
A. Yes.
Q. So you're familiar with that product, as well?
A. Yes, I use it.
Q. And how many products are within that line?
A. There are two products, NasalGuard scented and unscented, and then there's a spray product.
Q. And those are the products that are sold in the United States?
A. They're sold, I believe, in the United States as well as overseas.
Q. Do you know if there are any other NasalGuard products sold overseas?
A. I'm not familiar with that.
Q. Okay. Do -- are you familiar with the

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formulation and the ingredients of the NasalGuard product?
A. Yes.
Q. Do they all have the same formulation?
A. Yes, with the exception of the scented component. I'm referring primarily to the composition for the product that's sold in the tube.
Q. And what's different about the scented composition?
A. Just that it contains a scent as opposed to unscented.
Q. And do you know what that scent is?
A. I don't use the scented product, I'm sorry.
Q. But other than the scent that's included in the scented formulation, it's your understanding that the formulation and composition of all the Trutek NasalGuard products are the same?
A. Yes.
Q. And are you familiar with the specific ingredients that are used in NasalGuard?
A. Yes.
Q. And how do you know that information?

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A. They're listed in the patent, the '802 patent. And, also, if you visit the NasalGuard website and you click on the ingredients, they're listed there, as well.
Q. And the ingredients that are listed on the website, do they provide the specific amounts of each ingredient that are included in the NasalGuard product?
A. No.
Q. So it's just a list of ingredients?
A. Yes.
Q. And do you know the specific amount of each ingredient that's used in NasalGuard?
A. No.
Q. Have you ever asked for that information?
A. Excuse me?
Q. Have you ever asked Trutek for that information?
A. Yes.
Q. Did they provide it to you?
A. Yes. And percentages.
Q. Okay.
A. Not the quantification. So, in other words, what I'm saying is that of 100 percent,

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they'll tell me how much of every ingredient is, but not the specific quantities that are used.
Q. Okay. So you have -- so you are aware of the percentage of the entire composition for each ingredient --
A. Yes.
Q. -- of NasalGuard?
A. Yes.
Q. And when was that information provided to you?
A. Within the past two weeks.
Q. So you did not have the information about the percentage of the individual ingredients within the NasalGuard products prior to preparing your reports; correct?
A. Only the information that was available online.
Q. And that would be just the list of ingredients without their percentages?
A. That's correct.
Q. And why did you ask for the percentages for the ingredients two weeks ago?
A. For further clarification. These matters are usually -- they're usually private or considered confidential. And so in order to

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prepare for this deposition, I felt it necessary to have a better understanding of those amounts.
Q. But you didn't think it was necessary to have an understanding of the amounts or the percentages at the time that you formed your opinions as stated in your reports?
A. Well, the percentages were available to me at that time, but the amounts were not.
Q. Okay. Let's back up. I thought you said that you received the percentages two weeks ago?
A. Yes, but the percentages are on the website.
Q. Okay. Earlier you testified that the website only has the list of ingredients, not the percentages; is that correct?
A. Yes. All right. I misspoke, I'm sorry.
Q. That's okay. I know it's -- it can be tough keeping track of everything, especially when I keep peppering you with questions. And, you know, I apologize for that. If you need me ever to restate my question just to make sure you understand it, I'm always happy to do that. Okay?
A. Thank you. I appreciate that.
Q. I also have the advantage of being able

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to see everything written out while you'll just have to listen. So I know it's difficult.
Okay. So let's just back up to make sure I understand. The website includes the list of ingredients, but not the percentages; correct?
A. That's correct.
Q. And you had that information about the list of ingredients at the time of preparing your expert reports; correct?
A. That's correct.
Q. Okay. You did not have the percentages of the ingredients or the actual amounts of the ingredients at the time of preparing your reports; correct?
A. Well, I relied on the information that was in the patent. So there are -- there is in the Wahi '802 patent, there are tables that include all of the ingredients or any permutation of those ingredients in the ten different -- I'd have to specifically, if I have it here, pull it up so that I could take a look at it.
Q. Yeah, we can pull that up right now.
A. Yeah.
MS. PETERSON: Can we pull up the exhibit that was previously marked as Exhibit 2.

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THE REMOTE TECHNICIAN: Yes, stand by, Counsel.
(Deposition Exhibit 2, Previously Marked.)
THE REMOTE TECHNICIAN: It's on the screen.
BY MS. PETERSON:
Q. Okay. And is it also -- Dr. Lemmo, if you don't have a copy handy, if you go to the chat, you should be able to open up a copy of the patent, as well, directly if it's easier for you to scroll through it.
A. All right.
Q. Or we could ask Jennifer to scroll through to the tables. What would you prefer?
A. Yeah, if Jennifer can scroll through it, it will make it easier for me because I'm opening a lot of windows here, and I prefer not to. If you scroll down --
MS. PETERSON: Yeah, I think we want to go to the fourth page of the PDF, starting with Column 5.
BY MS. PETERSON:
Q. Are these the tables you were referring to?

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A. These are the tables I'm referring to, yes.
Q. Okay. And where -- specifically which table contains the formulation for NasalGuard?
A. I don't have the exact reference to the table for that because each is that it contains -- it could contain this ingredient, the other ingredient, et cetera. So I don't have that information handy to say that it's Table 2 or Table 4 or whatever.
Q. Okay. But to your understanding, does at least one of these tables in the '802 patent contain the exact list of ingredients in NasalGuard?
A. I believe so.
Q. Okay. Now, if you look at the tables, you see that for many of the ingredients that are listed they're provided with a range, a percentage range; correct?
A. Yes.
Q. Okay. So is it fair to say that with respect to the specific NasalGuard formulation, you don't know the precise percentage of the ingredients, but rather just what ranges are reported in the tables of the '802 patent?

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A. Yes.
Q. Okay. So you had this information -- certainly you had the '802 patent in your possession and considered it in forming your opinions as stated in your expert reports; right?
A. Yes.
Q. Okay. At the time you prepared your reports, did you know which exact table of the '802 patent matched with the NasalGuard formulation?
A. No.
Q. Okay. And you also did not know the specific percentages of the ingredients in NasalGuard at the time that you prepared your reports; correct?
A. Correct.
Q. Okay. Did you not think it was necessary or important to have an understanding of the percentages of the ingredients in NasalGuard at the time that you formed your opinions provided in this matter?
A. At the time I formed my opinion on the matter, I focused on specific things that were recited in the claims.
Q. Okay. But you didn't think it was

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important to have an understanding of the specific percentages of ingredients contained within NanoBio Protect in the course of forming your opinions; is that right?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Can you just clarify that for me, I'm sorry?
BY MS. PETERSON:
Q. So at the time that you formed your opinions as stated in your reports, you didn't think it was important to understand the specific percentages of ingredients contained within NanoBio Protect?
A. Yes.
Q. And what about the ingredients for -- oh, I'm sorry, I might have -- I asked a bad question there. Let me try that again.
At the time that you formed your opinions as stated in your reports, you didn't think it was important to understand the specific percentages of ingredients contained within Trutek's NasalGuard product?
A. Yes.
Q. And I think I had asked you that same

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question with respect to NanoBio Protect. So let me just clarify that.

When you prepared your -- formed your opinions and prepared your expert reports, did you know the specific ingredients that were contained within NanoBio Protect?

A. Not the specific ingredients, the -- there was one ingredient that I primarily focused on and that was benzalkonium chloride.

Q. Okay. But you were not aware of any of the other ingredients contained within NanoBio Protect when forming your opinions and preparing your expert reports; correct?

A. That's correct.

Q. And would it be fair to assume, then, that you were also not aware of the percentages of the ingredients contained within NanoBio Protect when forming your opinions and preparing your expert reports?

A. Yes.

Q. Did your assignment in this matter include anything other than assessing and providing opinions on whether NanoBio Protect infringes the '802 patent claims?

A. No.

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Q. So you are not offering any opinions concerning the validity of the '802 patent?

A. The validity of the '802 patent relative to the claims that it makes?

Q. Well, you understand that a patent has a number of claims at the end of it; right?

A. Yes.

Q. And those claims are what defines the invention?

A. Yes.

Q. And is it your understanding that for an infringement analysis, you have to compare those claims and all of the elements to the accused product to determine if they're all present?

A. Yes.

Q. And you also understand that those patent claims could be found either by the patent office or by a court or by a jury to be invalid under any number of invalidity grounds?

A. Yes.

Q. So, for example, like obviousness, anticipation, enablement, are you familiar with -- or have you heard of those terms before?

A. Yes, I've heard of the terms.

Q. So are you offering any opinions in this

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matter relating to those issues of invalidity, for example, in response to Dr. Amiji's report?

A. I believe I did.

Q. And are all of your opinions on the subject matters of -- or the issue of infringement and patent validity, are those contained within your three expert reports?

A. Yes.

Q. Okay. Let's go ahead -- actually, let's skip that for now.

Dr. Lemmo, what did you do to prepare for your deposition?

A. I reviewed the materials that are -- that I wrote, and I reviewed the exhibits that you provided or were provided to me by Mr. Kremen.

Q. And what exhibits were those?

A. The list of exhibits that were -- that we referred to such as this one, '802 patent, as well as the statements by Dr. Amiji in his reports and the other documents that accompanied that group. So there was a list of exhibits.

Q. Okay. The list of exhibits, is that something that was contained in one of the expert reports in this matter, or is that a list that was prepared by Mr. Kremen?

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A. It was the list that was supplied by Mr. Kremen.

Q. Okay. Did you review the deposition transcript of Dr. Amiji to prepare for today's deposition?

A. Yes.

Q. Now, the documents that were provided to you that you reviewed in connection with your preparation for this deposition, did you receive any documents that you hadn't already seen before?

MR. KREMEN: Objection to the form of the question.

THE WITNESS: I'm curious what you're referring to. Because I did receive the patent, which is one of the documents in the packet and the statements from Dr. Amiji so that I could provide a response to that. So I don't know if there was anything else that you're referring to.

BY MS. PETERSON:

Q. Okay. So -- well, I'll break it down. So in preparation for your deposition, Mr. Kremen provided you with some documents; correct?

A. Correct.

Q. Okay. Had you seen all of those documents before in the course of your preparing

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your expert reports?
A. Not all of them.
Q. Okay. What documents were new?
A. Some of the documents related to the terminology referring to the use of the word "inhibition" or "inhibiting" versus the term "preventing."
Q. Okay. Anything else?
A. Offhand, I would have to look at my list of documents to be specific. I'm using two computers because I keep everything on electronic. You have to forgive me.
Q. No problem.
A. But I have to pull it up on the other computer.
The -- let's see, I have the notice of deposition. I believe that was for Dr. Amiji.
Q. Okay. And, Dr. Lemmo, just to be clear here, I don't need you to read the list of everything.
A. Oh.
Q. I'm just wondering if there was anything new that you reviewed in preparation for your deposition that you had not already considered when forming your opinions and preparing your

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expert reports?
A. No.
Q. Okay. Thank you.
Did you meet with anyone to prepare for your deposition today?
A. No.
Q. Did you meet with Mr. Kremen at all to prepare for the deposition?
A. We spoke on the telephone.
Q. Okay. How long did you speak with Mr. Kremen on the telephone?
A. In total, maybe two to three hours.
Q. Was anybody else present for that conversation?
A. No.
Q. Did you have any conversations with Mr. Wahi in preparation for your deposition?
A. I believe so, yes.
Q. And what did you discuss during that conversation?
A. Again, it focused primarily on the '802 patent and the statements of the claims. Just the clarification, once again.
Q. The clarification of what exactly?
A. The terms that are used in the claims.

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Q. So a clarification of his understanding of the claim terms as the named inventor on the patent?
A. My understanding of what he stated in his claims.
Q. Okay.
A. So that we were -- I'm sorry. So that we were on the same page, that I, in fact, read the claims accurately.
Q. Okay. And in terms of what -- when you say what he stated in the claims, you're talking about what Mr. Wahi stated in the claims as the named inventor on the patent?
A. Yes.
Q. Okay. Did you meet with Mr. Altman or have any phone conversations with Mr. Altman to prepare for your deposition?
A. I don't know Mr. Altman.
Q. Okay. You never --
A. I've never spoken with Mr. Altman.
Q. Okay.
A. I don't know who he is.
MR. KREMEN: Are we on any line of questioning that we can't interrupt for just a break? Because we've been going for an hour. I

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think Dr. Lemmo needs -- might need a little bit of a break, unless you want to continue on.
MS. PETERSON: Yeah, let me just ask, like, one or two more questions, and then that will be a great breaking point.
BY MS. PETERSON:
Q. And then just to confirm, did you meet with or have any conversations with anybody else at Trutek to prepare for your deposition?
A. No.
Q. And approximately how much time did you spend reviewing the materials and the reports and the deposition transcript to prepare for your deposition today?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Can you just spell it out for me again?
BY MS. PETERSON:
Q. Yeah. How much time did you spend personally preparing for the deposition today?
A. Oh, to read everything -- I'm a slow reader, I'm sorry. To read everything and just to review, to refresh my memory, because some of the documents are a few months old, I would say

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five hours. But that's not a solid five hours. It's when I have the time to read different documents, I did.

Q. Okay. Thank you.

MS. PETERSON: Why don't we go off the record.

THE VIDEOGRAPHER: We're going off the record. The time is now 11:03 a.m.

(Recess from the record.)

THE VIDEOGRAPHER: We're back on the record. The time is now 11:13 a.m.

BY MS. PETERSON:

Q. Welcome back, Dr. Lemmo.

A. Thank you.

Q. Have you been asked to provide any opinions on anything else beyond what has been contained in your three expert reports?

A. No.

Q. Okay. Now, you have submitted three reports in this case; right?

A. It was three or four. I forget. But I think it was three.

Q. Okay. So let's go ahead and mark and identify those for the record.

MS. PETERSON: So we will mark as

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Exhibit 13 a copy of Dr. Lemmo's opening report.

(Lemmo Deposition Exhibit 13 was marked for identification and attached to the transcript.)

THE REMOTE TECHNICIAN: Stand by.

BY MS. PETERSON:

Q. Dr. Lemmo, do you recognize Exhibit 13 as your opening report?

A. I believe so, yes.

Q. And looking at page 16 of the PDF, is that your signature?

A. I can only see the first page. If Jennifer can move that just to confirm it.

Yes, that's my signature.

Q. Okay.

MS. PETERSON: And then let's mark as Exhibit 14 a copy of Dr. Lemmo's responsive report.

(Lemmo Deposition Exhibit 14 was marked for identification and attached to the transcript.)

THE REMOTE TECHNICIAN: Stand by.

BY MS. PETERSON:

Q. Dr. Lemmo, do you recognize Exhibit 14 as your expert report responsive to and in

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rebuttal of defendant's opening expert report of Mansoor M. Amiji?

A. Yes.

MS. PETERSON: And if we could turn to page 14 of the PDF, please.

BY MS. PETERSON:

Q. Is that your signature, Dr. Lemmo?

A. That's my signature, yes.

Q. And the report is dated August 23rd, 2022?

A. Yes.

MS. PETERSON: And then let's mark as Exhibit 15 a copy of Dr. Lemmo's reply expert report.

(Lemmo Deposition Exhibit 15 was marked for identification and attached to the transcript.)

THE REMOTE TECHNICIAN: Stand by.

MR. KREMEN: Can we see a little more of that.

Can we see a little bit more of what's on that page because all I see is the caption.

MS. PETERSON: Yeah, can we scroll down a little bit on that page? There we go.

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BY MS. PETERSON:

Q. Dr. Lemmo, do you recognize Exhibit 15 as a copy of your reply expert report, specifically in reply to defendant's expert report on noninfringement?

A. Yes.

MS. PETERSON: And then if we could turn to page 13 of the PDF.

BY MS. PETERSON:

Q. Is that your signature, Dr. Lemmo?

A. Yes.

Q. And this report was dated September 29, 2022; correct?

A. Yes.

Q. Okay.

MR. KREMEN: Liane, are we going to include -- add as an exhibit his declaration on claim construction?

MS. PETERSON: Yeah, I have that. I'll bring it up later.

MR. KREMEN: Okay. Fine. I just wanted to know. So we have four documents total from Dr. Lemmo; right?

MS. PETERSON: I'm focusing on the expert reports currently, but later we'll look at

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the declaration.
MR. KREMEN: Sure.
BY MS. PETERSON:
Q. Dr. Lemmo --
MS. PETERSON: Actually, if we could go back and pull up Exhibit 14 now. This is the responsive report.
And let's take a look at the second page. Yeah, right there. If we could scroll down a little bit to see the -- okay.
BY MS. PETERSON:
Q. So now, with respect to the validity of the '802 patent and responding to Dr. Amiji on these issues, Dr. Lemmo, you've offered four opinions in this responsive report; correct?
A. Yes.
Q. And those would be the level of skill in the art, scientific and technical aspects of the "hold" function of the '802 patent, enablement of the disclosure in the Rolf prior art publication --
MS. PETERSON: And then if we scroll down to the next page.
BY MS. PETERSON:
Q. -- the fourth topic is the relevance of

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the commercial success of Trutek's products.
A. Yes.
Q. Those are the four opinions that you've offered in response to Dr. Amiji's opening report?
A. Yes.
Q. Does Exhibit 14, your responsive report, contain all of the opinions that you have formed directed to the issues of validity of the '802 patent?
A. Yes.
Q. And does your responsive report contain a complete statement of all the bases for your opinions?
A. Yes.
Q. Are there any statements in your responsive report that constitute the opinions of others?
A. No.
Q. And did you make any assumptions in formulating the opinions provided in your responsive report?
MR. KREMEN: Objection to the form.
THE WITNESS: I don't understand what you mean by "assumption."

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BY MS. PETERSON:
Q. Well, in reaching the opinions and conclusions that you've stated in the report, did you have to make any assumptions about anything?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: I'm not really clear as far as what you're asking me.
BY MS. PETERSON:
Q. Okay. And just to be clear then, this report contains all of your opinions on invalidity, meaning you're not providing any -- you have not been -- or you have not provided any opinions directed to anticipation of the '802 patent?
A. There's a report that talks about those terms relative to anticipation and obviousness. Is that what you're referring to?
Q. I'm asking you if you have offered any opinions in this report or formed any opinions as shown in this report on the issue of anticipation?
A. I believe I did.
Q. Okay. Can you identify where that is?
A. I'd have to scroll through the report. I'm only seeing -- I'm only seeing a short form

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here. And I believe this is -- I can't scroll through the report.
THE REMOTE TECHNICIAN: Counsel, I can give him access to --
MS. PETERSON: Okay. That's fine.
THE REMOTE TECHNICIAN: -- control, and he can scroll on his own --
MS. PETERSON: Sure.
THE REMOTE TECHNICIAN: -- if that works for you.
Dr. Lemmo, will that work for you?
THE WITNESS: We'll try.
THE REMOTE TECHNICIAN: Okay. Stand by.
Now, you should be able to with your mouse take control. If you click on the document, you should be able to take control.
THE WITNESS: A person having ordinary skill. We talked about the "hold" function. Just bear with me with this as I scroll through it.
This is the discussion of Rolf and what commercial success indicates.
Okay. Okay. I think I'm getting that confused with another document where I do talk about anticipation and obviousness.

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BY MS. PETERSON:
Q. Okay. What document is that? Because I haven't seen that in any of your reports.
A. All right. No, I think Dr. Amiji talks about it, and I think I responded to it.
Q. Okay. That's correct. Dr. Amiji did talk about anticipation --
A. Yeah.
Q. -- and obviousness.
A. Yes.
Q. However, you are not responding to those issues of anticipation or obviousness in your responsive report marked as Exhibit 14; correct?
A. That's correct.
Q. Okay. And you also did not form any opinions responding to Dr. Amiji on issues of Section 101 or otherwise known as subject matter eligibility; is that correct?
A. That's correct.
Q. And you also did not form any opinions responding to Dr. Amiji on issues under Section 112, including written description, utility, or enablement; is that correct?
A. That's correct.
MR. KREMEN: Objection; calls for a

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legal conclusion.
MS. PETERSON: We can take that exhibit down.
BY MS. PETERSON:
Q. Now, you've submitted two expert reports on issues of infringement. That would be your opening report and your reply report; right?
A. Yes.
Q. Okay. And do those two reports, your opening report and reply report, contain all of the opinions you formed on issues directed to infringement?
A. Yes.
Q. Do the opening and reply reports contain a complete statement of all of the bases for your opinions?
A. Yes.
Q. And are there any statements or opinions in your opening report or reply report that constitute the opinions of others?
A. No.
Q. Dr. Lemmo, did you draft your three expert reports that we just marked as Exhibit 13, 14, and 15 by yourself, or did you have assistance?

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A. No, I drafted them myself.
Q. Are there any portions of any of the three reports that you did not draft yourself?
A. No.
Q. And I'm sorry, I might be going back over something we already covered, but just to make sure, you are aware that Trutek has retained Mr. Haidri to also opine on issues relating to invalidity.
Is that your understanding?
A. Yes.
Q. Okay. Did you have any conversations or any meetings with Mr. Haidri when either he was working on his responsive report or when you prepared your responsive report?
A. No, I've never had a conversation with Mr. Haidri.
Q. Okay. Have you reviewed Mr. Haidri's report?
A. No.
Q. Do you know why you were asked to only address certain of the issues in response to Dr. Amiji on issues of invalidity?
MR. KREMEN: Objection to the form of the question.

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THE WITNESS: Maybe you could rephrase that for me.
BY MS. PETERSON:
Q. Okay. Well, you understand that Dr. Amiji offered opinions on invalidity of the '802 patent; right?
A. Yes.
Q. And you reviewed his report; correct?
A. Yes.
Q. But you did not form opinions in response to each of the issues raised by Dr. Amiji; correct?
A. Correct.
Q. Okay. Do you know why you were asked to only address those four issues that are contained in your responsive report?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Maybe you could rephrase that for me again, sorry.
BY MS. PETERSON:
Q. Why did you only respond to those four issues in your responsive report?
A. I think they were most important. Those were the four most important issues.

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Q. Those were the four most important issues in terms of having a disagreement with Dr. Amiji?
MR. KREMEN: Objection to form.
THE WITNESS: If we could just take a look at those four, not necessarily a disagreement with Dr. Amiji, but to express my opinion.
BY MS. PETERSON:
Q. Okay. So I just want to understand the basis for your understanding that those were the four most important issues. Why were they important to you?
A. If we could -- you know, if we could pull those up, this way I could --
Q. Yeah, let's go back to Exhibit --
A. That would be great.
Q. Yeah.
A. Yeah, that would be great.
MS. PETERSON: Exhibit 14 -- Exhibit 14, page 2, please.
THE WITNESS: Yeah, that will make it easier for me. Okay.
BY MS. PETERSON:
Q. Actually, you know what, let me ask you another question first. For these four issues you

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addressed in your responsive report, did you identify these issues, or were you asked by counsel to provide your opinion on these four topics?
A. I think it was a combination of both.
Q. Did counsel for Trutek ask you to provide opinions on any other issues beyond these four with respect to the invalidity of the patent?
A. Not to my recollection, no.
Q. Okay. Yeah, I think that answers my question.
MS. PETERSON: So we can take that down.
THE WITNESS: Okay.
MS. PETERSON: Let's mark as another Exhibit -- we'll mark this as Exhibit 16. Let's pull up a copy of Dr. Lemmo's CV.
(Lemmo Deposition Exhibit 16 was marked for identification and attached to the transcript.)
MS. PETERSON: Jennifer, this is identified as No. 6 in the file.
THE REMOTE TECHNICIAN: Yes, I see it. Thank you.
BY MS. PETERSON:
Q. Okay. Dr. Lemmo, do you recognize

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Exhibit 16 as a copy of your CV?
A. Yes.
Q. Do you have any changes to make to it, or is it current?
A. That's current.
Q. Do you have any patents?
A. No.
Q. And have you ever published any articles?
A. Yes.
Q. Scientific papers?
A. Yes.
Q. Okay. Are those publications listed in your CV? I don't think they are.
A. I don't think so.
Q. Okay. Approximately how many papers have you published over the last -- or in general, do you know a rough number?
A. Not that many. The publications related to my degrees, my dissertation research, as well as my master's degree, and also publications that were either in the form of newsletters, booklets that were asked of me by corporations to write or internal documents. So in total, I would say 10 to 15 would be a maximum number.

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Q. And what about any -- like any conferences, did you -- have you ever prepared or given any abstracts or any presentations at conferences within your field of study?
A. Yes.
Q. Approximately how many?
A. A presentation of my research work for my Ph.D., as well as my research work on my master's degree. I've also served as an invited speaker at various conferences, professional meetings. But, again, it's not -- it's based upon materials that were part of the conference. So, for example, I would give lectures on various aspects of nutrition or aspects of the corporate sector and how science and regulatory affairs are integrated into the development of products.
Q. Okay. And just to confirm, those aren't listed in your CV either; right?
A. That's correct. I did not list that.
Q. Okay. So, Dr. Lemmo, I believe you described yourself as a consumer health care corporate consultant; is that right?
A. Yeah, a consumer health care related to products that are sold over-the-counter, OTC products primarily.

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Q. Okay. And would that primarily relate to products such as nutritional supplements and vitamins, so products in those categories?
A. Yes, those as well as some other categories, primarily in the area of homeopathic medicines and some other roles that I've been involved in in the -- for example, in BioBalance, a probiotic product that was used in the treatment of specific kinds of conditions, gastrointestinal disorders.
Q. And what do you -- just so we can be clear on terminology, what are you referring to as homeopathic medicines?
A. Homeopathic medicine is the use of natural remedies. They're extracts of botanicals. These are used as tinctures. And in Eastern European traditions, homeopathy is a very significant part of medicine. And so I've given lectures on homeopathic medicine, you know, both in a corporate setting as well as in professional meetings.
Q. Okay. And you have a bachelor's degree in chemistry; right?
A. That's correct.
Q. And a master's and a Ph.D. in nutrition

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science; right?
A. That's correct.
Q. Okay. And it looks like you have for the last 15 years, primarily, you've been acting as a consultant for a consumer health care corporate consultant?
A. Yes, and also working in academia, you know, as an either part-timer or full time for a college or university in the vicinity.
Q. Okay. And those -- the college teaching experience that you have, that is listed in your CV; right?
A. Yes.
Q. Is that complete?
A. Yes, it is.
Q. Okay. Now, looking --
MS. PETERSON: Could we scroll down to the third page.
BY MS. PETERSON:
Q. Do you see there's a heading here that says "Corporate Consulting Experience"?
A. Yes.
Q. Now, I only see one consulting assignment here listed within that time frame after 2007. Is that the only consulting job you

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had over that time frame, from 2007 to the present?
A. Consultant -- well, the only one that's not there is Trutek. So in 2011, I served as a consultant for Matrixx Initiatives.
Q. Okay.
A. And then the -- that's correct. There's no other consulting that was done other than those two. Because it was mostly academic work that I did.
Q. Okay. So from 2011 to the present, you have the consulting work obviously with Trutek, and then the rest of your, I guess we'll just say employment, for use of a better term, that's been with respect to your academic teaching assignments?
A. That's correct. Because for the most part I've been retired since 2000 -- let's see, 2018. So I reached retirement age in 2018. And so I simply do consulting work at this point. I no longer do academic work.
Q. Okay. And then have you done any other consulting work since 2018 apart from the consulting services provided to Trutek?
A. No.

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Q. Okay. So looking at this most recent corporate consulting experience you have listed for Matrixx, I see there's one item identified as relating to an oral zinc product; is that correct?
A. Yes, that's correct.
Q. Okay.
MS. PETERSON: If we could go back and look at the first page.
BY MS. PETERSON:
Q. So the consumer health care corporate consultant work from 2007 to the present, that's been focused on the Matrixx assignment and the work with Trutek; right?
A. Correct. Or if a colleague or someone I knew in the corporate sector reached out to me to review a product and just to provide them with some guidance, particularly for claim construction or regulatory affairs, it might have been something that surfaced but it was nothing significant and I did not really include that.
Q. Okay. You provided consulting services for claim construction? Did I hear you correctly?
A. Yes, claim construction on a product. Primarily, if a company wants to market a product, I'll use an example of a dietary supplement, there

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are guidelines that the company must follow in order to make the claim that it has adequate substantiation attached to the claim.

Q. I understand. Okay.

A. So that's essentially it.

Q. Okay. Thank you.

Okay. So then prior to that, you were with BioBalance Corporation, and that involved the probiotic product you mentioned earlier?

A. Yes.

Q. Okay. And then it looks like you were with Wyeth Consumer Healthcare in product development for about six years; right?

A. That's correct. Until the company was purchased by Pfizer.

Q. Okay. And your work at Wyeth with respect to product development, that was focused on, it looks like, a few brands: Solgar, Centrum and Caltrate; correct?

A. That's correct.

Q. Those are vitamins or calcium supplements?

A. That's correct.

Q. And then when you say that you managed the product development of those brands, what did

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that involve?

A. Well, it involves either the creation of new product -- if I could just backtrack, Solgar Vitamin and Herb Company was acquired by Wyeth Consumer Healthcare around the time -- I believe it was 1998, and I was hired by the company to kind of head up their scientific division for that division.

In addition to that, I was employed by Wyeth in their business development unit in the evaluation any products that would be coming into the OTC area as one of the scientists who worked on that team.

So I provided expertise, opinions on the validity of the products that would be presented to be incorporated into the portfolio, as well as if the company was interested in doing acquisitions of the business or acquisition of a product, I would be on that review team.

Q. Okay. And so that work focused on evaluating the technical aspects of the products?

A. Yes.

Q. And would it be fair to say that in the course of your product development work while at Wyeth, it was not focused on actually developing

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new formulations or products in the laboratory?

MR. KREMEN: Objection to form.

THE WITNESS: Well, it did include supervision of the laboratory, as well as the formulation of the product within the manufacturing sector. So if I could elaborate, my function was in the creation of a new product to work with both the analytical segment of the company, and those were more of the pharmaceutical people, as well as the manufacturing element of the concept so that the concept, the idea, would come to fruition as a finished product.

BY MS. PETERSON:

Q. Okay. Thank you.

And it looks like prior to that you were with General Nutrition Centers, GNC?

A. Yes.

Q. And your work there was directed to nutritional supplements?

A. Primarily, yes. The General Nutrition Centers, Incorporated, the retail outlets coast to coast, had a major presence particularly relative to the passage of the Dietary Supplement Health and Education Act, known as DSHA, and the company needed representation with respect to that

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litigation being finalized. So I played a major role for them in that respect.

But I also helped in the development or the change of focus of the product line so that it would incorporate more of the kinds of products that you see at GNC in today's market as opposed to at the time that I started there.

Q. And what were those new kinds of products that were being sold by GNC?

A. Well, I'll give you one example. The product that was known as Cold-EEZE, which is a zinc lozenge, very similar to the Zicam product, was presented to me by the inventor. And he wanted to market that product in a retail outlet. And so I had to review his data to substantiate the claims that he was making about his product. GNC did not decide to take that product into their portfolio, and so they had to market it elsewhere.

Q. Okay. And that would be an example of what you were describing earlier as a homeopathic medicine?

A. Yes. And they have a line of homeopathic products, as well, tinctures and other types of products along those lines that might have been used as more of the cosmetic area. And

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so you see that today in a lot of products where extracts of botanicals, et cetera, which are based on homeopathic medicine may be found in commercial products in today's market.

Q. Okay. And then your work at Pall Biomedical Products, that looks like it was focused more on the device side; is that correct?

A. Yes, Pall Biomedical Products was a very interesting assignment for me. Dr. David Pall was an expert in filtration systems. And the company was looking to move into the area of application in the biomedical field, so biomedical products or medical devices, so to speak.

And so the technology that Dr. Pall had created in his filtration technology was to be extended for applications primarily in a hospital, either in filtration of blood and other fluids or in the filtration of air particles, heat and moisture exchanges that would be given to a patient during the time that they were under anesthesia.

Q. And then, lastly, looking at ICN Pharmaceuticals, this looks like another assignment focused on nutritional supplements?

A. Yes, that was. ICN Pharmaceutical

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wanted to branch out into the traditional area, and so I was retained with the acquisition of what was known as Faraday Laboratories, it no longer exists, and brands that were primarily marketed to allied health professionals. And the majority of them would be in the chiropractic market.

Q. And then on the next page, it looks like there's one other piece of employment listed --

MR. KREMEN: Excuse me. The only thing that's visible on the screen is the first page of his résumé.

MS. PETERSON: Okay. Let's look at page 3, please. Can we turn to page 3.

BY MS. PETERSON:

Q. At the top here, it looks like this was your first employment experience listed at Pharmacia Laboratories. It looks like this was following your undergraduate degree?

A. Actually, this was during the time of my master's degree.

Q. Okay.

A. So I had an undergraduate degree, but this was a job that -- because Pharmacia was very closely located near Rutgers University, and they were interested in developing a product known as

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HEALON, which is hyaluronate acid. And it was primarily used for injecting into the joints of racehorses. And so my job was to do the blood analysis work, the samples, in the laboratory that I had at Rutgers University while I was a graduate student.

Q. Okay. And then looking at the rest of this page, your earlier consulting experience, would it be fair to say that that also generally relates to vitamins and other dietary supplements?

A. Yes, and primarily on a technical basis. Again, as I said, many of these products -- excuse me, many of these products were in need of technical support, whether it was documentation or support for claims that the company wanted to make, as well as advisement relevant to regulatory matters, and that's where I provided the help.

Q. Okay. Thank you for that.

So is it correct that you do not have any experience in the formulation or development of oil-in-water nanoemulsions?

MR. KREMEN: Objection to the form of the question.

THE WITNESS: Well, let me just use the example where in the vitamin industry, there are

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products such as the fat soluble vitamins that are -- utilize a delivery system that's known as a micellar complex. And so you take a fat soluble vitamin, and it's treated with surfactants or whatever in order to make it more water soluble or more miscible with the human body.

BY MS. PETERSON:

Q. Okay.

A. So that's essentially what my experience has been.

Q. Okay. And just to confirm, those products, those would be administered orally?

A. Yes.

Q. Not through the nasal passages?

A. No.

Q. Okay. And did you -- I mean, were you aware of these fat soluble vitamins just as a course of your work within the industry, or did you actually develop and formulate any yourself?

A. No, they were developed by other people, and I was -- I served as a scientific liaison to give an explanation of the technology of these other companies for the parent company that I was employed by.

Q. Oh, okay. So you became aware of these

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as a result of investigating them for potential acquisition by your employer?
A. That's correct.
Q. Okay. And so that would be the extent of your experience that you said related to oil-in-water nanoemulsions?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: I would say that my experience with that was twofold. That's the corporate side of it. But, also, on a personal level, in order to document what's going on, this is not a very simplistic concept for people in marketing and people in corporate positions. So I had to do a lot of investigating on my own about the technology. So I had to learn the technology myself in order to present it on behalf of that company.
BY MS. PETERSON:
Q. And what company was that presented to?
A. Well, that was presented in several companies. It was presented in ICN pharmaceutical, but it was also presented at General Nutrition Centers.
Q. Okay. And then I assume you don't have

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any experience in the formulation or development of oil-in-water nanoemulsions for nasal administration; correct?
A. That's correct.
Q. Okay. And you do not have any experience in the formulation or development of oil-in-water nanoemulsions for use as a vaccine adjuvant?
A. That's correct.
Q. And it sounds like you don't have any experience in the formulation or development of pharmaceutical compositions that are intended to be administered nasally to humans?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Maybe you could rephrase that for me.
BY MS. PETERSON:
Q. You do not have any experience in the formulation of pharmaceutical compositions that are intended to be administered nasally to humans?
A. My only exposure to that was with the activities at Matrixx and Zicam because Zicam had a product that was administered nasally.
Q. Okay. But the product that you

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consulted for Matrixx was an oral zinc lozenge product; correct?
A. Actually, it was -- at the time the portfolio included a nasal product, but I focused primarily on the oral zinc product.
Q. And you don't have any experience in the formulation or development of pharmaceutical compositions that are intended to inhibit or prevent infection caused by various bacteria?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: That experience, no. The experience -- hands-on experience in development, no.
BY MS. PETERSON:
Q. And is it correct that you do not have any experience in the formulation or development of pharmaceutical compositions to inhibit or prevent infection caused by viruses?
A. That's correct.
Q. Apart from your work on these two litigation matters for Trutek, is it correct that you do not have any experience in the formulation or development of pharmaceutical compositions to inhibit or prevent the nasal inhalation of any

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type of particulate matter into the nose?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: If I refer back to my experience with Pall Corporation, with the development of a medical device that was used for the respiratory system, that's the only experience that I can recall.
BY MS. PETERSON:
Q. And that would be -- since it's a medical device, that wouldn't be a composition that's applied directly to a patient's skin; correct?
A. No, it's applied directly over the nose as a mask.
Q. And I saw in your CV for Pall Biomedical that -- is it correct that this work was related to addressing issues of patients breathing cold dry gas during surgery?
A. That's correct.
Q. Okay. Is it correct that you do not have any experience in the formulation or development of pharmaceutical products intended to kill or inactivate bacteria or viruses within a human nasal passage?

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MR. KREMEN: Objection to the form of the question.
THE WITNESS: I have no experience of development of those types of pharmaceuticals.
BY MS. PETERSON:
Q. And you do not have any experience in the formulation or development of vaccines?
A. That's correct.
Q. And apart from your work in connection with this matter, you do not have any experience in the formulation of pharmaceutical products intended to capture and hold particulate matter within the nose or nasal passage?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Just -- can you repeat that question?
BY MS. PETERSON:
Q. So apart from the work that you're doing in connection with these litigations --
A. Yes.
Q. -- you do not have any experience in formulating or developing pharmaceutical products intended to capture and hold particulate matter within the nose or nasal passages?

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A. Yes.
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Yes, just simply what I referred to as far as the mask in Pall Biomedical.
BY MS. PETERSON:
Q. Okay. And that was a physical barrier, the mask; correct?
A. Yes, that's a filtration device of a certain dimension to trap particles.
Q. And is it correct that you do not have any experience in formulating or developing pharmaceutical products intended to capture and hold particulate matter within the nasal passage by means of electrostatic attraction?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Yes.
BY MS. PETERSON:
Q. And just to confirm, when you say yes, that means yes, that's correct, you do not have the experience?
A. Yes, that's correct.
Q. Okay. And the same is true for my other answers?

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A. Yes, it relates to anything that I've been employed. That's how I'm answering yes. So it's -- these are not situations where during the time that I was employed that I had experience with that type of application.
Q. Okay. Thank you.
And I would assume then that in addition to not having the experience in developing or formulating those types of products for those applications that you also wouldn't have any experience in testing those products either?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Testing the products would not be part of my assignments in any of my employment.
BY MS. PETERSON:
Q. Okay. And that would include any in vitro testing?
A. To my knowledge, yes.
Q. Okay. So in vitro testing would not have been part of your assignments for any of your work?
A. Correct.
Q. Okay. And in vivo testing in animals,

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that also would not be part of your work experience?
A. My only experience in vivo would relate to what I did at Pharmacia with the blood testing and for my doctorate and my master's degree where I did experimentation with animals.
Q. And what type of experimentation were you doing as part of your thesis work?
A. Body compositional analysis of the animals under specific types of dietary restrictions as well as focusing on calcium nutriture as it relates to the development of osteoporosis under stressful conditions.
Q. Okay. So that work also did not involve any testing or development or -- development of products intended to inhibit or prevent infection of disease in those animals?
A. No.
Q. Okay. Dr. Lemmo, do you consider yourself to have any particular expertise in patent law?
A. No.
Q. And you do not have an economics degree?
A. Economics?
Q. Yeah.

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A. No, no economics degree.
Q. You don't have an accounting degree?
A. No.
Q. And then with respect to your sales and marketing experience from your prior employment, was that focused on making sure that the claims made in those marketing or advertising materials complied with applicable regulations?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Well, let me explain. It did apply to the regulations, but it also applied to having adequate substantiation, scientific substantiation for any of the claims associated with the products that were marketed so that those -- the science evolves going forward, and so claims will expire. And my function was to make certain that the claims were substantiated in light of any new developments.
BY MS. PETERSON:
Q. So the marketing and advertising work was focused on substantiating the claims that were made in those materials with respect to the products?
A. Yes, and also training the marketing and

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salespeople regarding the product.
Q. Okay. And is it correct that you do not have any experience in developing or formulating pharmaceutical products to prevent infection caused by anthrax?
A. Yes.
Q. Yes, meaning you do not have that experience?
A. I do not have that experience, no.
Q. You also don't have any experience in developing or formulating pharmaceutical products to prevent infection or to inhibit infection caused by coronavirus?
A. I have no experience in that.
Q. Any experience with smallpox?
A. No experience in that.
Q. What about influenza?
A. Same, no experience in that.
Q. What about avian flu?
A. No experience in that.
Q. Swine flu?
A. No experience in swine flu.
Q. Rhinovirus?
A. Well, I've had rhinovirus. That's my only experience, but no, not in the development of

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that.
Q. What about any experience with chemical toxins?
A. You're referring to xenobiotics.
Q. Sure. That would be an example.
A. Pollutants, pollutants and ways to boost the immune system, but they would be primarily with products that would enhance the natural immunity of the body.
Q. Okay.
A. So in that respect, yes.
Q. And where did you do that work?
A. Well, those products would be at GNC.
Q. Okay.
A. That -- we did a line of product called cell support, and they were essentially antioxidant products that were developed.
Q. And then what about do you have any experience in developing or formulating pharmaceutical products intended to inhibit infection caused by fungal spores?
A. No.
Q. Okay.
MS. PETERSON: We've been going about an hour. Do you want to take a short break at this

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point?
MR. KREMEN: When do you want to -- do you want to break for lunch at any point?
MS. PETERSON: Let's go off the record.
THE VIDEOGRAPHER: We're going off the record. The time is now 12:05 p.m.
(Recess from the record.)
THE VIDEOGRAPHER: We're back on the record. The time is now 12:48 p.m.
BY MS. PETERSON:
Q. Dr. Lemmo, did you have any conversations with anyone on either of the breaks that we've taken today about the substance of your testimony that you've given?
A. No, I have not.
Q. Now, Dr. Lemmo, we touched on this briefly, but you have provided opinions on what you consider to be the appropriate level of skill of a person of ordinary skill in the art in this matter; right?
A. Correct.
Q. And what do you consider to be the field of the invention of the '802 patent?
A. Well, I see it really two ways. I see it essentially as a medical device, but as an

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application which could be considered like a cosmetic. But I do see it as a medical device.

Q. And you understand that the claims are directed to a formulation?

A. Yes, that's correct. But the method of delivering the formulation relates more in my opinion to a medical device.

Q. And how is the formulation to be delivered?

A. Well, as a medical device, since it's applied to the skin and not in the nose, per se, taken internally, I see it really as being something that you're using that's applied to the skin in the nasal passage area and possibly a small distance into the nose, but not necessarily something that is considered typically as a pharmaceutical agent that you would be either ingesting or somehow becoming more invasive.

Q. So would you consider all pharmaceutical products that are administered to the skin to be devices?

A. No. Some of them are topical agents that are specific for the treatment of skin conditions.

Q. And topical -- drugs that are delivered

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topically can also be used for systemic treatment, as well; right?

A. Yes, that's correct. Both in humans as well as in animals.

Q. And the formulation that's described in the '802 patent, it doesn't require any special device for a person to apply it to their skin around the nasal passages; correct?

A. That's correct. You could apply it with your finger.

Q. So if it's a gel or a cream, it would just be applied directly?

A. That's correct.

Q. And you also mentioned that it was similar to a cosmetic, but you understand that the claims also require, I guess what we would call, active ingredients to prevent or inhibit infection; correct?

MR. KREMEN: Objection to the form of the question.

THE WITNESS: The composition contains ingredients that are moisturizing to the skin. They may be emollients there that are moisturizing to the skin, and that's why I would consider that composition similar to a cosmetic.

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BY MS. PETERSON:

Q. But the object of the invention is not to moisturize the skin; is it?

A. No, it's not.

Q. The object of the invention is to inhibit infection by microorganisms in an individual?

A. I think it's to inhibit particle flow into the respiratory system. It doesn't restrict itself to microorganisms.

Q. Sure.

So microorganisms, though, are encompassed by the claims; correct?

A. Yes, anything that would be in the airflow stream that would be entering the respiratory system, according to the way I read it, would be included in that, yes.

Q. So that would include microorganisms; right?

A. Pollen, microorganisms, bacteria, viruses, animal dander, a number of items that potentially are in the airstream. There could be even pollutants, as I mentioned before, with the xenobiotics, chemical entity, smoke can all be in your airstream, depending on your environment.

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Q. And cosmetics aren't typically used to treat or inhibit infection caused by microorganisms or bacteria or viruses; correct?

A. Cosmetics are -- can you just repeat that? You said are --

Q. Cosmetic products are not typically used to treat or inhibit infection caused by microorganisms such as bacteria or viruses that enter the respiratory system?

A. Yes. Yes, I would consider cosmetics to be, as their name implies, either something that you're applying to the skin to improve the appearance or the condition of the skin. Essentially it's different.

Q. Okay. Now, I -- okay. So going back to your opinions on what you believe to be the person of ordinary skill in the art, has your opinion changed since you provided it in your reports?

A. Based upon what I've read, as far as its definition, and since I'm not legally trained on how it's used legally, I have to base my opinion on what I read. But I have not changed my opinion on what you consider to be a person of ordinary skill in the art.

Q. Okay. No, I just want to understand if

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your opinion is still the same as how it's explained in your reports?
A. Absolutely, I understand that. Yes, it's the same.
Q. Okay. And you said that your opinion was based on what you read. What materials did you read that informed your opinion?
A. Well, essentially, I went online to see what the definition is from a patent standpoint. There are references to both a person of ordinary skill, as well as a person of extraordinary skill. So I tried to educate myself before I wrote anything regarding an opinion on what I've read.
Q. Okay. And do you -- I don't think those online definitions were cited in your report. Do you recall what references or materials you viewed online to obtain this information?
A. Yeah, quite honestly, at this point I don't remember when I did that.
Q. Okay. And you understand that Dr. Amiji has offered a differing opinion of the level of skill?
A. Yes, I read his reports, and I do respect his -- you know, his experience and his comments, but I differ.

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Q. Yeah, I understand.
Do you consider yourself to be a person of ordinary skill in the art directed to the '802 patent under your definition?
A. Considering everything that I've read over time, I would have to exclude myself as a person of ordinary skill and more towards the person of extraordinary skill, since I've spent a good deal of time, not only in this particular case but in the previous case with Matrixx, trying to understand and grasp the concept.
Q. So that would be based on your research and the work that you did in forming your opinions in both the Matrixx litigation matter as well this present litigation matter?
A. Yes, and I --
MR. KREMEN: Objection to the form of the question.
THE WITNESS: You might want to repeat that question as far as I got into -- there was an interference, I'm sorry.
BY MS. PETERSON:
Q. I think you said it was -- your prior comment that it was based on the research and the work that you've done in forming your opinions in

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the Matrixx matter and in this matter.
Did I understand that correctly?
A. Yes, that's correct.
Q. Okay. I just want to make sure I didn't miss anything. You did not provide any opinions in this matter directed to infringement using Dr. Amiji's standard of a person of ordinary skill in the art?
MR. KREMEN: Objection to the form of the question.
BY MS. PETERSON:
Q. Let me rephrase.
So your opinions that you provided in this matter as reflected in your expert reports and in your declaration, you applied your understanding of the level of a person of ordinary skill in the art; correct?
A. That's correct.
Q. Did you provide any alternative or different opinions on those same issues but instead using Dr. Amiji's definition?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: No.

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BY MS. PETERSON:
Q. Okay. Let's pull up your responsive report.
MS. PETERSON: This is Exhibit 14. And we'll go to page 2 of the report.
And could we go down one page.
BY MS. PETERSON:
Q. Okay. So you see here on this page we have your section titled "A Person Having Ordinary Skill In The Art"; correct?
A. Yes.
Q. Okay. Looking at the last full sentence on this page, you state that the person -- actually, the POSITA -- could we use that phrase? Is that okay?
A. Yes, that's fine.
Q. Okay. So at the bottom of page 2, you state that the POSITA "is a person who does not possess special or distinct knowledge or capability in a discipline"; correct?
A. That's correct.
Q. And then going on, you explain, "This person would have a basic skill set or talent related to the technology related to the art"; right?

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A. Yes, that's correct.
Q. And so, in your opinion, it would be a technician?
A. A technician would qualify, yes.
Q. Okay. And I think if we look maybe four sentences down or so on the page, you say, "A PHOSITA is primarily a technician in his chosen field" --
A. Yes.
Q. -- "and his skills are those ordinarily associated with such a technician"; correct?
A. That's correct.
Q. Okay.
MS. PETERSON: If we could scroll down a little bit more to the bottom of this page.
BY MS. PETERSON:
Q. The last paragraph, it looks like you're drawing on your experience as a college professor. And it looks like teaching both students who are non-majors as well as students who are majoring in that particular discipline; correct?
A. That's correct.
Q. And is it your opinion that the POSITA for the '802 patent would be someone who took general courses in the relevant subject matter but

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did not major or focus on that field at any level?
A. That's correct.
Q. So all of this discussion that we just went through right now, that would be your general understanding of what a person of ordinary skill in the art should be?
MR. KREMEN: Objection to form.
THE WITNESS: The -- could you just repeat that question for me, I'm sorry?
BY MS. PETERSON:
Q. Yeah.
So all of those statements that we just went through, those reflect your general understanding of what a person of ordinary skill in the art should be?
A. Yes, the qualifications that I would consider.
Q. Okay. And the basis for that understanding is in part based on what you reviewed online about the standard?
A. My readings and I think from my experience in product development as far as the basic concepts that are employed by in getting a product from concept to finished product, the people who would be involved in that process and

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their level of -- their level of sophistication or level of education that they need in order to carry out that function.
Q. Okay. Did Mr. Kremen or any other counsel for Trutek provide you with any explanation or framework for how to determine the level of skill for a POSITA as it relates to the '802 patent?
A. I've had discussion with Mr. Kremen regarding the person of ordinary skill from the legal standpoint just to see if, in fact, in reviewing the material, you know, if I was on the right track, I was explaining it correctly.
Q. Okay. And the -- those legal stand -- let me start over.
The legal framework or guidelines or framework that Mr. Kremen provided to you, you don't have that explained or set out in your report; correct?
A. That's correct.
Q. Okay. Now, in the laboratory setting, what is your understanding of the difference between a technician and, say, you know, someone with more experience who's running the lab or supervising the research?

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MR. KREMEN: Objection to the form of the question.
THE WITNESS: You might have to rephrase that for me.
BY MS. PETERSON:
Q. Well, you've said that you think the appropriate level of skill is that of a technician, and so I just want to understand, you know, what is a technician? Like what are their basic qualifications, especially relative to other people with more experience?
A. Okay. Based on my professional experience in the corporate setting, the laboratory was headed or directed by a person who would be a Ph.D. level scientist. That person would be my peer as a Ph.D. scientist who is in charge of the development product -- the development of products. But carrying out responsibility of getting the concept to the steps necessary to either quantify or quality of the materials used in the product would be individuals who would be at a lower level.
On the manufacturing side, the person who would be formulating the product, making the physical product from the concept that I designed,

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developed, created, whatever terminology you wish to use, that individual may not have an advanced degree but has the experience or capacity to carry it out from the concept that I explain to the finished product that the consumer would receive.

Q. Okay. So the technician then that you're referring to, that would be someone who on the manufacturing side has the experience necessary to carry out the instructions for how to make the product, how to formulate the product; right?

A. Yes. For example, if a product has to be produced in a specific dosage form -- tablet, capsule, liquid, whatever -- and there is equipment involved, that technician would know about binder, fillers, other agents that might be necessary to get the concept of the active ingredient that I want to create in this product into a form that maintains its stability and in a form that will be easy and understandable by the end user.

Q. And so the technician would then primarily be someone who is following directions provided by the more experienced supervisor?

A. Yes, or from me, as far as the

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appearance of the product that I'm looking to create, whatever the case may be. Or that person might, in fact, as you say, go to a supervisor and get advice from that individual from a more technical standpoint, yes.

Q. Would a technician typically be designing their own experiments, or would they be looking to the supervisor for input on that type of work?

A. I think you've got two things working here. The technician could carry out the experimentation because it's almost like a cookbook for the experimentation. It doesn't really require a person -- if you've been doing this, you pretty much know how to do it from that standpoint. From the manufacturing standpoint, I think it's also the technician who could carry it out to get it through that process so that you have uniformity at the end.

Q. Okay. So on the experimentation piece then, the technician is able to conduct the experiment because he or she either knows what experiment to conduct and they've done it before or they're provided instructions that they're able to follow; is that right?

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MR. KREMEN: Objection to form.

THE WITNESS: The way I understand that, for what you're asking me, is that a person who's carrying out an experiment could carry out that experiment once they've had the experience as a reason -- not necessarily formal education experience. I could go back to also my statement regarding the student.

In my experience in teaching students laboratory procedure, the students should be able to, after the instruction was given by me, carry out those laboratory experiments, even though that student may not even have a degree.

BY MS. PETERSON:

Q. Okay. So as long as the required instruction is provided to the student or the technician, they should be able to carry out that experimentation?

MR. KREMEN: Objection to form.

THE WITNESS: They should recognize certain elements of what would be necessary to carry out the procedure.

BY MS. PETERSON:

Q. Would a technician or a non-major student typically be expected to design their own

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experiment to test a particular feature of a product if they haven't been given instructions or haven't had the experience in testing for that feature?

A. I could only address my own experience in that capacity. When I was a college student, one of the courses that I had to take was design of experiment. And so without an advanced degree, I essentially had to design an experiment. And of course it was presented to the professor to see whether or not I did it correctly. But the answer is yes, you can definitely design experiments. You can do things or carry out procedures accordingly, even though the person may not have an advanced degree.

And just as a follow-up to that, in reading some of the comments by Dr. Amiji on a person of ordinary skill, he does comment in a similar way to me in his report on invalidity, and he clearly stated that a person of ordinary skill in the art would know about things like viscosity and relative to the term of "adequate impermeability."

So I think there's definitely somewhat of an understanding here. You know, this term --

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this term is something that needs to be interpreted so we can have some agreements regarding that. And I would refer you essentially to his report on invalidity. I think it was page 51, as I remember, because I remember reading that.

Q. Okay. Would a student taking a certain course outside of his or her major typically be expected to be familiar with scientific literature in that field outside of what is taught in the course?

A. That's really subject to the professor whether -- in my courses, for example, I always provided students with opportunity to visit the library and do independent study, whether they were majors or not. So, you know, I feel that that's part of the learning process to learn on your own as opposed to just reiterating what the professor has taught. It creates for you an independent thinker.

Q. And going back to the laboratory or the manufacturing setting, if a technician were to run into a problem or an issue in carrying out the concept or the instructions, would they typically look to that more experienced supervisor for

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advice or guidance on how to address the issue?

A. I would encourage that. If the technician comes back to me, for example, with choices of a component that I would like to use in the product and suggests to me that this would work better but it's in the same category, I would give that person the opportunity to go ahead and do that, go forward and use that as a substitute. And I've done that in my experience.

Q. Okay. I think my question was a little bit different, directed to a circumstance where a technician runs into a problem, like the instructions that were provided aren't working. What would the technician do next? Would they go to the supervisor for --

A. Yes.

Q. -- input on how to correct that problem?

A. Yes, I would expect them to.

Q. Now, I think you also explained that it is your understanding that the POSA also knows of and understands all of the prior art in his field of endeavor; correct?

A. Yes.

Q. Okay. So if a claimed invention is new and not described in the prior art, then that

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knowledge and understanding of the prior art would not necessarily inform the POSA about how to make and use the claimed invention; right?

MR. KREMEN: Objection to the form of the question. If you understand it.

THE WITNESS: I don't understand the question. You might want to clarify that for me.

BY MS. PETERSON:

Q. So we have, you know, a claimed invention described in a patent and it's new, it's not described in the prior art. So just having knowledge of the prior art would not necessarily inform the person of skill about how to make and use the claimed invention; right?

MR. KREMEN: Objection to form.

THE WITNESS: I think it's a matter of the terminology that's used.

BY MS. PETERSON:

Q. Well, I guess another way to look at it is if the instructions or explanation for how to make and use the claimed invention are not in the prior art, then they would have to be provided directly in the patent; correct?

A. I think that's a matter of patent law. So I would agree. But that should not preclude

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the person from learning from reading the patent, even though it's novel.

Q. No, understood. Absolutely, you can read and -- I agree with you.

A. Yes.

Q. You can read and understand what is explained in the patent.

A. Yes.

Q. Okay. Is it also your opinion that the person of ordinary skill in the art must necessarily be able to make and use the claimed invention?

A. Again, I'm not clear on making and using the claimed invention. Maybe can you just give me a clarification on that again, I'm sorry?

Q. Sure. Give me one second because I think this is --

A. Sure.

Q. -- mostly a direct quote from your report.

A. Sure. Yeah, if you identify where it is, I can read the statement again. This way I'm clearer.

Q. Okay. Let's take a look at -- oh, we're on the right page, page 3.

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MS. PETERSON: Can we scroll up to the top?
BY MS. PETERSON:
Q. The second full sentence, you state, "He must have sufficient experience in his art so as to become competent and understand and interpret the prior art related to a patent so that he can make and use the invention described and claimed in the patent."
A. Yes.
Q. So that's your opinion?
A. Yes, it is.
Q. Okay.
A. Yeah. Yeah, I wasn't sure what you were referring to. Thank you for identifying it.
Q. I was paraphrasing. I should have pointed directly to the report, I apologize.
A. Not a -- no need to.
Q. But just to understand, so it is your opinion that a person of skill in the art will necessarily be able to make and use the claimed invention as described in the patent?
A. Yes.
Q. Now, all of this is in contrast, I think, to what you described as an extraordinary

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skilled person?
A. Yes.
Q. And that would be someone who has an advanced degree?
A. Yes, and I think who qualifies as a person of advanced skill in the area. There are many individuals who I respect and read their scientific views on things, and those are the people that I consider to be extraordinary.
Q. Okay. And that extraordinarily skilled person could also be a student who is majoring in that particular subject matter?
A. Yes, I think that a person who is extraordinary in their skill has some fundamental knowledge of concepts. In this particular case, some of these concepts are essentially taught to us in a high school setting or in an undergraduate setting. And then based on those skills or that knowledge, that person can proceed to reach an advanced degree but always hold on to those basic skills.
Q. Okay. Let's move forward two pages to page 5.
A. Okay.
Q. And I think here on page 5, now you're

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providing your explanation as to the specific level of skill possessed by a person of ordinary skill in the art for the '802 patent; correct?
A. Yes, that's correct.
Q. And so specifically, it would be the level of skill of that of a chemical or a pharmaceutical formulator?
A. Yes. And as I said previously, it could be an individual who is not classified in that terminology or in that manner but could be an individual who, again, has read extensively on the subject matter.
Q. Okay. And then you set out two qualifications for the person of ordinary skill in the art; correct?
A. Yes, I have two related but separate qualifications, yes.
Q. Okay. And the first qualification, is that after reading the '802 patent, he should be able to create the formulations described in the patent; right?
A. Yes, that's stated.
Q. And then the second qualification is that the person of skill in the art must be positioned in time just prior to the effective

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filing date of the '802 patent; right?
A. Yes.
Q. So that's referring to the time period that we're looking at as opposed to any particular qualifications of the person of ordinary skill in the art?
A. Yes.
Q. Okay.
A. And my thought -- you know, that's just a reflection of my thought process at the time. So at the time we have to go back to that year, or whatever year we're looking at, what was the level of knowledge within the scientific community related to the subject.
Q. Okay. And then you provide some additional explanation on this same page indicating that the person of ordinary skill in the art would have the skill and experience to duplicate the formulations listed in the '802 patent; right?
A. Yes.
Q. Okay. And then looking on the next page?
A. Page 6?
Q. Yep.

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A. Yes.
Q. The very last sentence, you explain, I think what you identified, as your key requirement for the person of ordinary skill in the art; is that right?
A. Yes.
Q. And that would be the required experience --
MR. KREMEN: Where are we?
THE WITNESS: Page 6. Page 6, first paragraph.
MS. PETERSON: There you go.
BY MS. PETERSON:
Q. Okay. So the key requirement, in your opinion, is that the person of ordinary skill in the art is -- has acquired experience -- or it is the acquired experience necessary to create a wide variety of formulations from the class of ingredients disclosed in the '802 patent; right?
A. Yes, that's what I described earlier, where if there are options that as stated, if you remember our previous conversation relative to the '802 patent with the various tables of ingredients, but they identify categories, and so that person of ordinary skill in the art would be

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able to decipher or understand the various options that they have available to them as recited in the patent.
Q. Okay.
MS. PETERSON: We can pull that exhibit down.
BY MS. PETERSON:
Q. And let's go back and take a look at Exhibit 2. This is the '802 patent.
A. I think I have a copy instead of an electronic copy here. It's easier for me to read.
Q. Yep, that's fine.
A. My eyesight in my advanced years is -- it's easier to look at it here. I have it.
Q. Okay. So you've reviewed the '802 patent in its entirety; right?
A. Yes.
Q. The specification as well as all of the claims?
A. Yes.
Q. Okay. And let's take a look at Claim 1.
MR. KREMEN: Can we do that on the screen?
BY MS. PETERSON:
Q. So it will be page 6 of the PDF.

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Okay. So looking at Claim 1, it starts out with what we call a preamble. That would be the opening phrase.
Do you see that?
A. Yes.
Q. And it refers to "A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film"; correct?
A. That's correct.
Q. Okay. And then following that there are three other claim elements, A, B, and C; right?
A. Yes.
Q. And I think those are what you refer to respectively as capturing, holding, and killing; is that right?
A. Yes, it's a -- forgive me for doing that, but it's how I try to convey messages sometimes to an audience that may not be scientifically directed. So it's a habit.
Q. Okay. And then looking at Claim 2, Claim 2 is very similar to Claim 1 except that it recites a formulation instead of a method; right?

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A. That's correct.
Q. Okay. And in addition to those elements of Claim 1 that we just walked through, Claim 2 also adds the express requirement that the formulation contains at least one cationic agent and at least one biocidic agent; right?
A. That's correct.
Q. And then if we look at Claims 6 and 7, which are at the bottom of the page, those are dependent claims where the cationic agent and the biocidic agent specifically are benzalkonium chloride; right?
A. That's correct.
Q. Or in the case of Claim 7, the biocidic agent can be benzalkonium chloride or Lysine HCL?
A. Hydrochloride, correct.
Q. Okay. Now, you understand that because these claims use the word "comprising" that the formulations can also include additional ingredients; right?
A. Yes.
Q. Okay.
MR. KREMEN: Calls for a legal conclusion.

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BY MS. PETERSON:
Q. And you would also agree that Claims 1 and 2, they do not just recite a formulation having certain ingredients; right?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Well, Claim 1 is a method.
BY MS. PETERSON:
Q. Yeah, it's a method of using a formulation; right?
A. Yes, you said Claim 1 and 2.
Q. Okay. So -- but Claim 1 does refer to a method of using the formulation; right?
A. Yes.
Q. Okay. And you agree that Claims 1 and 2 do not just recite a formulation having certain ingredients or a method of using a formulation having certain ingredients; right?
MR. KREMEN: Objection to the form.
THE WITNESS: Your question is a little bit confusing to me if you could restate it.
BY MS. PETERSON:
Q. Okay. Let's look at just Claim 2.
Would you agree that Claim 2 does not just recite a formulation having certain

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categories of ingredients?
MR. KREMEN: Objection to form.
THE WITNESS: In Claim 2, if we look at that information, it's -- it doesn't really spell out exactly what you're saying, I think. I may be a little bit confused as far as how you're interpreting that claim.
BY MS. PETERSON:
Q. Okay. Well, it doesn't read a formulation containing a biocidic agent and a cationic agent period. There are other elements to the claim; right?
A. Yes.
Q. So the formulation that is described in Claim 2 also has another -- has a number of other elements or functions that the formulation will perform; right?
A. Yes, and they're recited in the tables in the body of the patent.
Q. The ingredients are recited in the tables?
A. Yes, that's correct.
Q. Okay. But looking at Claim 2, Claim 2 recites specific functions that the formulation should be able to perform; right?

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A. That's correct.
Q. It must be able to electrostatically inhibit harmful particulate matter from infecting an individual through nasal inhalation?
A. That's correct.
Q. And the formulation must also be applied to the skin or tissue of nasal passages in a thin film?
A. Yes, that's correct.
Q. And Claim 2 also requires that the thin film applied or formed upon application of the formulation must electrostatically attract particulate matter to the thin film?
A. That's correct.
Q. And the claims also require that the thin film must hold the particulate matter in place?
A. Correct.
Q. And the formulation must also provide adequate impermeability to the thin film?
A. Correct.
Q. Okay. So those are all functions that the claim requires the formulation to provide; right?
A. Correct. Yes.

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Q. And those same functions are recited in Claim 1, as well; right?
A. That's correct.
Q. Okay. Now, I think we all understand this, but is it your understanding that all cationic agents will have a positive charge?
A. Yes.
Q. Okay. And the functions recited in the claims of electrostatically inhibiting and electrostatically attracting, those are the results of the positive charge of a cationic agent; right?
MR. KREMEN: Objection to the form.
THE WITNESS: Of the formulation.
BY MS. PETERSON:
Q. So it's the positive charge of the formulation?
A. Yes.
Q. Okay. So you understand that even if a particular formulation includes a cationic agent with a positive charge, that other components or ingredients in the formulation could impact the overall charge of the formulation?
MR. KREMEN: Objection to the form of the question.

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THE WITNESS: You may want to clarify that.
BY MS. PETERSON:
Q. So the formulation we're talking about here, it doesn't just exist of only a cationic agent; right?
A. That's correct.
Q. Okay. And you understand that other ingredients in the formulation could impact the overall charge of the formulation; right?
MR. KREMEN: Objection to form.
THE WITNESS: Other ingredients are in the formula and may contribute cationic charge.
BY MS. PETERSON:
Q. And they could also make the charge lower, as well; right?
A. If the ingredient is neutralizing the cation.
Q. Okay. Yeah. So there could be ingredients included in a formulation that could neutralize the charge of the cationic agent altogether; right?
A. It depends on the amount that's present in the formula.
Q. Okay. And would you also agree that the

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pH of a formulation could impact the charge of the formulation?
A. Yes.
Q. And the pH of the environment where the formulation is applied could also impact the surface charge; right?
A. Yes.
Q. Okay. So we also understand from Claims 1 and 2 that the formulation is being used in a manner to inhibit harmful particulate matter from infecting an individual through nasal inhalation; correct?
A. That's correct.
Q. And the '802 patent provides examples of those harmful particulate matters; right?
A. That's correct.
Q. And it includes things like anthrax, spores, various viruses like coronavirus, smallpox virus, influenza, avian flu, swine flu, and rhinovirus?
A. I would classify all of those as negatively charged particles.
Q. Sure. But the patent describes a wide variety of different viruses.
A. Yes.

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Q. Okay. The patent also describes a number of biological or chemical elements, toxins, and irritants, as well, that can be addressed by the claimed invention; right?
A. Yes. Yes, that's correct.
Q. And the '802 patent also describes preventing or inhibiting the infection of airborne microorganisms?
A. I think the correct term here is "inhibiting" them.
Q. Okay. So the '802 describes airborne -- or the '802 patent describes airborne microorganisms as another example of harmful particulate matter that the claimed invention is intended to inhibit the infection of; right?
A. If it's an infecting agent, yes.
Q. Also airborne fungal spores?
A. Any agent that would be in the airstream at a concentration when a person is coming in contact with it with a concentration of those particles are irritants, negatively charged items, they would all be classified as those that would come in contact with the formulation and be rendered, held onto as it states in Claim 1, Section B. So that holding aspect is a very

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important aspect of what's claimed here.
Q. Okay. And still looking at the types of harmful particulate matters identified by the '802 patent, there's also a group of bacterial diseases that are identified for which infection can be inhibited; right?
A. Yes, absolutely.
Q. And that would include the bacteria that are responsible for causing whooping cough, meningitis, diphtheria, pneumonia, tuberculosis, and anthrax?
A. Yeah, any of the bacteria that would have a membrane structure that you've recited would be affected by virtue of the cationic nature of the formulation.
Q. Oh, okay. So, in other words, the -- it's that membrane structure -- that membrane structure would be disrupted by the cationic agent or the biocidic agent?
A. That's correct.
Q. Okay. And as long as the harmful particulate matter is negatively charged, then the claimed invention will capture and hold those harmful particulate matters, as well?
MR. KREMEN: Object to form.

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Which claim are you talking about, 1 or 2?
MS. PETERSON: Both.
MR. KREMEN: Okay. You can answer.
THE WITNESS: Yes, in 1, we're talking about attracting because of the charge difference and then holding it and essentially reaching that point of adequate impermeability where the product then -- or the bacteria, if that's what we're referring to -- becomes inactivated by means of the agents that are present. And that inactivation is essentially going to apply to those negatively charged particles that are in the airstream that could potentially create a problem for the individual.
So it's just a matter of looking at it from a particulate matter standpoint. And that's why I used the expression earlier that I viewed it more as a medical device that happens to employ a formulation. If I've made myself clear.
BY MS. PETERSON:
Q. I'm not sure that that was clear, but that's okay. We can move on.
A. Okay.
Q. So benzalkonium chloride, you're

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familiar with that agent; right?
A. Yes. Yes, I am.
Q. And when you used as a biocide, it works by disrupting or breaking up the cell membrane of an organism; right?
A. That's correct. That's correct.
Q. So it won't have the same effect on something where the cell membrane isn't present or protected, like in a fungal spore or an anthrax spore; right?
A. If there was a membrane --
MR. KREMEN: Objection to form.
THE WITNESS: If there was a membrane present, we're looking at what -- let me give you an example. If you're looking at enveloped viruses, there are some that have a membrane. Others do not. So what you're looking at is the effect -- and it's a chemical effect, essentially, of the action of the benzalkonium chloride on the membrane of the microorganism that we're questioning.
BY MS. PETERSON:
Q. Okay. And that biocidic activity of benzalkonium chloride, that's something that's been known and it's been used for that purpose for

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decades; right?
A. Oh, I believe since the 1930s from the literature that I've read on the subject, yes.
Q. Okay. Let's take a look at Column 4 of the patent.
MR. KREMEN: You have to scroll up. Keep going. One more.
MS. PETERSON: Yeah, so down at the bottom of that page. If we can go all the way down to the bottom.
BY MS. PETERSON:
Q. Do you see at the very bottom, starting at line 65, the '802 patent describes a formulation of the invention comprises and then there's a list of ingredients, including water, at least one quarternary thickener --
MS. PETERSON: And then if we scroll down --
BY MS. PETERSON:
Q. -- a preservative, a conditioner, an emulsifier, a biocidic agent, and a neutralizing agent added to adjust and achieve a pH in the range of 5.0 to 6.8?
Do you see that?
A. Yes.

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Q. So to function as described in the claims of the '802 patent, does the formulation need to have all of those ingredients?
A. I believe they do. That it does, yes.
Q. And then you mentioned this earlier, but the patent goes on and includes ten tables describing typical formulations; right?
A. Yes.
Q. Okay. And it's not a specific individual formulation disclosed in those tables, but rather a list of ingredients with ranges for the amounts of each ingredient; right?
A. Yes.
Q. So within each table, there can be some variation in terms of how much of each ingredient is used; right?
A. Yes.
Q. So would it be fair to say then that the patent lists more than just ten discrete formulations?
A. Multiples. In the cases of each of the tables it can give you a variety of choices.
Q. Yeah, because I think water is the primary ingredient in most of these, and it ranges anywhere from 52 to 88 percent; right?

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A. Yes. And it's an important component for the other materials to function.
Q. Okay. And then these tables include anywhere between 12 to 18 ingredients each; right?
A. I would safely -- I haven't counted them, but I would safely say yes. I assume that you did count it to give me that number. That's fine.
Q. It's pretty specific.
Okay. And then I saw that a few of the tables also list benzalkonium chloride?
A. Yes.
Q. And benzalkonium chloride is always identified in the range of .25 to 1 percent.
A. Yes, I think that's related to the standard that's allowable.
Q. Okay. So is that the effective concentration of benzalkonium chloride that's needed to function in the claimed invention?
A. I believe so.
Q. Okay.
A. Yes.
Q. Okay.
MS. PETERSON: We could take that down.
MR. KREMEN: It's now 1:47. Do you

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think we might want to have a break at this point?
MS. PETERSON: Yeah, sure, we can do that.
MR. KREMEN: Ten minutes?
MS. PETERSON: Yep, that's good.
THE VIDEOGRAPHER: We're going off the record. The time is 1:48 p.m.
(Recess from the record.)
THE VIDEOGRAPHER: We're back on the record. The time is now 2 p.m.
BY MS. PETERSON:
Q. Okay. Dr. Lemmo, I actually had just one other follow-up question about the formulations listed in the '802 patent.
A. Sure.
Q. Would you agree that varying the percentage of the ingredients listed in those formulations can change the potency of the formulation?
A. It depends on the ingredient, yes. So that if, for example -- I don't see it in the -- you know, I've have to scan it again. But if in the case of benzalkonium chloride, if it's exceeding that threshold limit, that could be very irritating for the user and, therefore, that may

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present itself as more of a problem than a benefit associated with using that ingredient in the formula.
Q. Okay.
A. So in any formulation, regardless if it's nutritional or otherwise, we, in formulating the product, have to consider what is the tolerance level for ingredients and what would be the benefit level to effect the outcome of the formulation.
Q. Sure.
And so, likewise, varying the percentage of the ingredients could also change the potency or the efficacy of the formulation; right?
A. Absolutely. Absolutely.
Q. And varying the percentage of ingredients could also change the consistency of the formulation?
A. Yes, it could fall out of uniformity. And that's why in many instance stability studies are conducted on formulas when they are conceptualized to the point where, as we were speaking before, are brought into the laboratory setting for the testing that's required to demonstrate uniformity of dose and consistency of

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ingredient and stability studies. That's all something that would then be evaluated that the formula does, in fact, do what you claim it's going to do.
Q. And changing the ingredients or the percentage of the ingredients could also have an impact on the adhesive properties of the formulation?
A. If it's one of the ingredients that is associated with either adhesion or cohesion, the answer is yes.
Q. Okay.
MS. PETERSON: Let's pull up Dr. Lemmo's claim construction declaration, and we will mark this as Exhibit 17.
(Lemmo Deposition Exhibit 17 was marked for identification and attached to the transcript.)
THE REMOTE TECHNICIAN: Stand by.
BY MS. PETERSON:
Q. Dr. Lemmo, do you recognize Exhibit 17 as a copy of your declaration in support of Trutek Corporation's claim construction brief?
A. Yes, I do.
Q. Okay. And if we move to the last page.

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Is that your signature?
A. Yes, that is. And it's dated September 24th, 2022.
Q. Okay. And do you see up at the top of the page there's a header in blue that indicates it was filed on September 27th, 2022?
A. Yes, I see that.
Q. Okay. Now, I notice that you do not have a separate list of materials that you reviewed in connection with preparing this declaration; correct?
A. That's correct.
Q. Is everything that you considered or reviewed in forming the opinions expressed in the declaration mentioned directly in the declaration?
A. Yes. I'd have to just review that document again as we go through it.
Q. Okay. Well, as of right now, are you aware of anything else that you reviewed in connection with preparing this declaration that you didn't identify?
A. No.
Q. Okay. And of course you prepared this declaration in support of Trutek's claim construction positions in the litigation; right?

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A. Correct, yes.
Q. Okay. Let's go back to page 2. And, actually, we're going to be -- actually, page 3. Let's go to the next page. This paragraph 5 -- nope, one page earlier.
MR. KREMEN: Liane, unfortunately, the page numbers are hard to read. So I guess if we could also identify the page by just the first sentence on the top, it would be helpful.
MS. PETERSON: Yeah. And where there's a clear paragraph number, I identify it that way so that there's no ambiguity. It's just for Jennifer sometimes it's easier to go to the page of the PDF so we can move through the document quickly.
BY MS. PETERSON:
Q. But looking at this page, which I think is page 3, we have paragraph -- do you see paragraph 5C?
A. It got cut off at the bottom.
MR. KREMEN: It's 5C, though; right? Okay.
MS. PETERSON: 5C.
MR. KREMEN: E or --
MS. PETERSON: C as in cat.

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MR. KREMEN: Yeah. Right.
BY MS. PETERSON:
Q. "Based on the disclosures," you see that?
So, Dr. Lemmo, in this declaration you're expressing the opinion that the claim terms, "electrostatically inhibiting," "electrostatically attracting," "adequate impermeability," and "renders said particulate matter harmless" are sufficiently clear and unambiguous; correct?
A. That's correct.
Q. Okay.
MR. KREMEN: You're --
THE WITNESS: Particularly to a person of ordinary skill in the art.
BY MS. PETERSON:
Q. Okay.
A. And that's what I referred to earlier for this terminology relative to Dr. Amiji's report.
Q. Okay. So that was the standard that you applied here, "sufficiently clear and unambiguous to a person of ordinary skill"?
A. Yes, that's correct.

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Q. Okay. So let's move ahead to paragraph 32, which is going to be page 13 of the PDF.
MR. KREMEN: 32.
THE WITNESS: Thank you for increasing the print size.
MR. KREMEN: Yeah, that helps.
THE WITNESS: It's very helpful.
MR. KREMEN: That really helps.
THE WITNESS: It's a lot of eyestrain.
BY MS. PETERSON:
Q. Okay. And here, Dr. Lemmo, you're referring to what you discuss as the "hold" function?
A. Yes.
Q. Of the claimed invention?
A. Yes.
Q. And you say that holding is based on the adhesive and cohesive properties of the formulation?
A. Yes, that's correct.
Q. Okay. And looking at the next paragraph, 33, where you're talking about adhesion, the very last sentence you state that, "This sets up a barrier of impermeability" --
A. Correct.

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Q. -- that -- "trapping a significant" -- let me -- the entire sentence reads that, "This sets up a barrier of impermeability trapping a significant number of these particles outside the nasal passageway"; right?

A. Correct.

Q. Okay. So the claimed formulation, once applied, it creates a thin film on the surface of the skin; right?

A. That's correct.

Q. And that thin film, as recited in the claims, is impermeable, meaning that it creates a physical barrier?

A. It -- yes, it creates a physical barrier outside of the body.

Q. Okay. And then that physical barrier traps those harmful particles from being inhaled into the respiratory system; right?

A. That's correct.

Q. Okay. Let's move ahead two pages to paragraph 37.

In paragraph 37, you conclude that the claim term "adequate impermeability is a property of the applied formulation that allows the harmful particles to be held in place for a sufficient

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time to be inactivated"; right?

A. That's correct.

Q. Okay. And so like we just talked about, that's a physical barrier that allows the harmful particles to be held in place --

A. That's correct.

Q. -- for a sufficient time? Okay.

A. That's right.

Q. Now, "sufficient time," that's another relative term; right?

A. Yes. Again, we don't know when an individual will come in contact with a harmful microorganism that's in the airstream. So as I remember, the statements regarding the use of the product is to use the product for a specific period of time before a person may want to reapply.

Q. And then what does the patent say about how much -- what does the '802 patent say about how much time is sufficient?

A. I believe it was a four-hour window. I have to go back and check that to be exact.

Q. So you think four hours is specified in the patent.

A. For the use of the ingredients, I

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believe it's four hours. You know, a lot happens within a four-hour window. So I believe that's what -- you know, what's -- but I'm not certain. You know, don't hold me to that one.

Q. Is it possible you're thinking of marketing claims of the products that you looked at in the case?

A. Thinking about it, it may not have been in the patent itself that I specifically saw that. It was probably on the website for the product.

Q. Okay. So to the best of your knowledge, the patent doesn't define how much time is sufficient to hold the harmful particles in place to allow them to be inactivated; right?

A. Yeah, at this point that's what I'm assuming, yes.

Q. Okay. So, I mean, how much time is sufficient? Is an hour good enough?

MR. KREMEN: Objection to form.

THE WITNESS: It's very vague. That's a very vague question of how much time. Because as I said earlier, I use the product. I use the product primarily during times when I'm in the company of strangers, but in my own home where I am now speaking to you, I'm not using the product.

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So I don't feel that I need it. I may be coming in contact with animal dander, but I'm not sensitive to the animal dander just because I have two cats.

BY MS. PETERSON:

Q. Okay. So the amount of time that is sufficient, I guess it depends on the circumstances of where the individual is or the particular sensitivities of the individual or even the nature of the material that's in the air?

A. I would --

MR. KREMEN: Objection to form.

THE WITNESS: I'm sorry, I didn't hear what --

MR. KREMEN: I said objection to the form of the question.

You may answer.

THE WITNESS: Okay. Just repeat, I'm sorry, I lost my train of thought.

BY MS. PETERSON:

Q. Okay. So the amount of time that's sufficient, it depends on the circumstances; right?

A. Yes, I agree with that, yes.

Q. Okay. So it could depend on where the

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individual who's using the product is located?
A. Yes. If you're in a highly polluted area, not necessarily pollution relative to bacterial pollution but irritants that may be in the air, if you happen to visit a place where people are smoking and you're highly sensitive to cigarette smoke or tobacco smoke, that may be a benefit for a person to possibly reapply. But I can't say definitely because I haven't done that testing.
Q. So the amount of time that's sufficient, it could depend on the environment. It could depend on the particular sensitivities of the individual, as well; right?
A. Yes.
Q. It could also depend on the nature of the material that's in the air; right?
A. Yes.
Q. So certainly --
A. Humidity. Humidity.
Q. I'm sorry, I cut you off.
A. No, humidity, a number of things that -- you know, a person might actually touch their face a number of times, and by touching the face affect that which they applied. Not everyone can say

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without touching their face for a significant period of time. There are studies that demonstrate that. Exactly, Liane.
Q. I do it all the time.
A. Thank you for demonstrating.
Q. I just broke my rule. I was just wiping my nose for people reading the transcript.
A. Okay.
Q. Okay. So in turn, that sufficient time -- I think you've also explained that the impermeability of the film is also related to this concept of allowing enough time to hold those particles in place; right?
A. Yes, and it's also the stickiness, the tackiness of the material that plays an important part relative to the cohesive property of the material. And it's that cohesive property that sets up that impermeable barrier. And that's -- when considered with the adhesive property and the cohesive property, as the patent states, that's the ability to hold. And it's essentially holding it outside of the body as opposed to depending upon that which is naturally present in the nostrils to try to protect an individual along with their immune system. That's how I interpret

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it.
Q. Okay. So the cohesive property is what sets up the impermeable barrier; right?
A. Along with that adhesive property. I think it's a combination of the two.
Q. Okay. And then how --
A. Because it's a -- I'm sorry, because it's a thin film.
Q. Okay.
A. So I think you have to have both, the ability to hold it to the skin and at the same time have that cohesive property that will act to attract any of those harmful agents, particles, that might be in the airflow.
Q. Okay. So the impermeable barrier is a result of the adhesive and cohesive properties of the formulation?
A. That's how I interpret it, yes.
Q. And those adhesive and cohesive properties can be different depending on the ingredients and the percentages of those ingredients in the formulation; right?
A. Yes.
Q. Which in turn can impact the level of impermeability?

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A. Probably, yes.
Q. And the ability of -- or the amount of time that the thin film acts as a barrier?
A. Correct. But these would all be tests performed on the product beyond the scope of the patent. So, in other words, what I reiterated previously, in my experience in getting products on the market, if you have to do testing of your product, you have to -- in order to make the claims for your product, you need to generate the substantiation to support what you're saying about the product.
So if I were putting a product on the market and I say reapply in four hours, I'm not taking that as an ambiguous period of time. I'm basing that on some sort of test parameter that I conducted in my laboratory or in the laboratory of the company before I go ahead and market that concept commercially.
Q. Okay. And I think at the beginning of that answer you referred to that as being tests performed on the product beyond the scope of the patent. So is that referring to the fact that the patent doesn't describe any such testing of any of the formulations listed in the patent?

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A. Well, it proposes -- the patent proposes the concept of how it's going to work and its methodology. Okay. There -- I don't think that it's necessary to provide in the patent the end point, you know, what exactly you're going to see clinically. It's essentially presented as the concept in the patent and then any subsequent information that I'm referring to in the testing would be done post patent, if that makes it clear.

Q. Okay. But just even more simply, the patent doesn't describe the results of any testing of that nature of any of the formulations that are listed; right?

A. No.

Q. Okay. Let's look at paragraph 39. Here, you state that the specification has a list of the formulation's generic ingredients.

Do you see that?

A. Yes.

Q. So this would be the categories of ingredients; right?

A. That's what I referred to previously, and I believe that's in the patent. It's recited in the patent.

Q. Okay. And is it your understanding that

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each of these are required in order for a formulation to function as claimed in the patent?

A. I believe so, yes.

Q. So a quarternary thickener would be necessary?

A. Yes, and that would be benzalkonium chloride that would be utilized. And some of these components may have multiple roles. That so benzalkonium chloride may act as a thickener but it may also act as a preservative and it may also act in the capacity of the cation contributor. It will also act as the biocide.

Q. Okay. And conditioner would be required for the formulation to function as claimed in the patent?

A. Yeah, I believe that's there primarily because it's coming in contact with the skin and so that certain ingredients or certain components -- as a formulator you would anticipate, you know, how the product is going to be used and that you don't want to apply something to the skin that's going to be irritating to the skin.

Also, sometimes ingredients, in order to blend together, you know, when you're making

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combinations, require certain components that might facilitate a better mixing of the ingredients and holding together. It's kind of like a jar of mayonnaise, you don't want -- you can make your own mayonnaise and it can separate out, but if you do it correctly, it should be consistent.

Q. And an emulsifier would be required in order for a formulation to function as claimed in the patent?

A. Yes.

Q. And a neutralizing agent is necessary for a formulation to function as claimed in the patent?

A. In that specific range, yes.

Q. Okay. And an emollient would also be necessary to function as claimed in the patent.

A. Yes, because it's applied to the skin.

Q. Okay. Looking at the next page -- well, actually, just starting at 41, here you're talking about the ten example formulations in the patent; right?

A. Yes.

Q. Okay. And then moving on to the next page, you state, "As long as the composition of

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ingredients remains within the specified ranges, the example formulations should function as disclosed."

Do you see that?

A. Yes.

Q. Okay. And what's the basis for that statement?

A. That is what I mentioned earlier so that, if I go back to my benzalkonium chloride -- sometimes people will abbreviate that as BZK, just so that it's not a mouthful of words. But essentially what I'm saying is you really want to have a level of ingredient that is safe and effective as two key components. You don't want to exceed that because it can potentially be irritating.

Remember, it's used as a disinfecting agent, and if you touch detergent or some other caustic material, you can get skin irritation, and degree of sensitivity varies from person to person.

Q. Okay. I guess I was wondering about -- I also had a question about your conclusion that the formulations should function as disclosed as long as the ingredients remain within the

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specified ranges. So you're not offering the opinion that as long as the ingredients remain within those specified ranges, they will necessarily and will always function as claimed?

A. The ingredients should support the claim that's made for the product.

Q. I'm not sure I understand that.

A. So, for example, if you're including -- if you're including in your claim that the product contains a biocide, you should have a biocide in your product. And it should be at a range that is useful and applicable for that type of a product. That's essentially what I'm referring to.

Q. Okay. But we looked at the claims earlier, and the claims don't recite all of these different categories of ingredients; right?

A. Right. That's correct.

Q. Okay. So I guess what I'm asking is based on what I see you say in paragraph 41, it doesn't appear that you're providing the opinion that as long as the ingredients in those ten formulations remain within the specified ranges, they will necessarily function as claims in the '802 patent?

MR. KREMEN: Objection; form.

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THE WITNESS: I'll try to clarify, if that's okay. Some ingredients in products -- and you'll see this on labels -- are considered inert. They are really not there for a specific functional property, but they are inert because they're needed as a vehicle or a protective agent or a cohesive agent, whatever that might be.

So certain ingredients are placed, I'll give you an example, in some formulations to deliver simply a vitamin. You may put an ingredient that's nonnutritive because to deliver it, it would not be appropriate on its own. So you have to provide it with something else. So they facilitate -- as inert ingredients, they facilitate the delivery of the product. That's not site specific delivery, but just delivery of the product in the specified form.

So in this particular case where it is a thin film that's going to be applied in and around the nostrils, you don't want that material to drip out, go into the channel, whatever area of the face. You want it to remain in place, to hold it in place for a specific period of time. And ingredients facilitate each other in working kind of like a concert when a formulation is developed.

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BY MS. PETERSON:

Q. Okay. And so as long as you stay within the ranges in the tables of the patent, then the formulation should work. It should have the right level of adhesion and cohesion --

A. I would hope so.

(Cross talk.)

A. I would hope so, yes.

Q. And how do you -- do you know for certain that every formulation within the stated ranges will have that sufficient level of adhesion and cohesion in order to create an impermeable thin film that will work as described in the claimed invention?

MR. KREMEN: Objection; form.

THE WITNESS: But I will answer. It goes back to the categories. It goes back to the categories that were mentioned previously. For each recitation of the tables, I have not personally done any work to test if that will work the same, if Table 5 works the same as Table 7.

At this point for what I've been exposed to and what I've read, I cannot tell you in certainty that 5 and 7 will work identically. I assume that they do, but I haven't done any

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testing on it. It would be unfair of me to make that judgment.

BY MS. PETERSON:

Q. And what is that assumption based on?

A. My experience primarily, my experience in putting formulas together.

Q. Okay. So that assumption, it's not based on any information or testing that you read in the patent; right?

A. No, it's not.

Q. Okay. Let's go to the next page of your declaration. And do you see here there's a heading that says "Disputed Claim Terms of the '802 Patent"?

A. Yes.

Q. In this first paragraph, 45, you start off by saying, "I am not an attorney. I understand that the property of a claim being indefinite is a legal determination, which is in the province of the Court."

And then you go on to say, "I will opine on whether the disputed claim terms are sufficiently unambiguous to enable one of ordinary skill to understand and practice the inventions set forth in the claims."

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Do you see that?
A. Yes.
Q. Okay. So that last sentence, does that accurately describe the standard that you applied in forming your opinions?
A. Yes, because I'm not a patent attorney, and my experience with patents has been primarily to review patents that were presented to me to give an opinion on. And that may be related to my -- not necessarily my academic experience but more so in my corporate experience and as a consultant to advise people if this is junk science, does this mean anything, can you use it.
Many people would come to a corporation presenting their products or their concepts of a product or whatever in order to get the corporation to back it and to do the necessary support to do further testing. And so to protect the corporation, people like myself would be employed to do the evaluation. But I'm not an attorney. In every corporate setting I've worked with attorneys like yourself and Mr. Kremen, and they have asked me as many questions as you do, but not under these circumstances.
Q. So did Mr. Kremen provide you with an

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explanation of the legal standard that the court --
A. I had asked --
Q. -- uses to determine --
A. Yeah, I had -- I'm sorry.
Q. -- whether a claim term is indefinite?
A. I have asked him what the meaning is, yes.
Q. And did you include his explanation in your report?
A. In my own words, yes.
Q. Okay. And those words are what we read here on paragraph 45?
A. That's correct.
Q. Okay.
A. Again, as a non-attorney, it's very difficult for me to write legalese. I cannot do that. I tried my best, but I cannot.
Q. Okay.
MS. PETERSON: Let's go to the next page, please.
BY MS. PETERSON:
Q. Paragraph 48, here you're discussing the claim term "electrostatically inhibiting"; right?
A. Yes, that's correct.

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Q. So about halfway through this paragraph, you have a sentence that starts, "From the remainder of each of Claim 1 or 2."
Do you see that? It's about halfway through the paragraph.
A. Is it about halfway? I'm just trying to find the -- but you can go forward. I'll follow you.
Q. Yeah, I'm just going to read from your report. So you explain that, "From the remainder of each Claim 1 or 2, supported by the specification, the claim elements involve electrostatic fields" --
A. Yes.
Q. -- right?
Okay. So it's your understanding, then, that Claims 1 and 2 are directed to using these electrostatic fields; right?
A. The electrostatic field that's generated by the formulation, yes.
Q. Okay. And then you also go on to say that, "Claims 1 and 2 refer to electrostatic attraction, which is a well-known scientific phenomenon even to a high school physics student"; right?

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A. That's correct.
Q. Okay. And the formulation that's claimed in the '802 patent, it operates by this phenomenon of electrostatic attraction; right?
A. Yes, it's positive charged particles that attract the negative charged particles and repel all the positive charged particles that may be in the atmosphere.
Q. Okay.
MS. PETERSON: Let's move ahead two pages, and we'll look at paragraph 51.
BY MS. PETERSON:
Q. And, again, here you're viewing the claim term "adequate impermeability" in the context of what you describe as the "hold" function of the claims; right?
A. That's correct. I consider that to be one of the most important elements of the product.
Q. Okay.
A. Or the patent.
Q. Okay.
MS. PETERSON: Let's go on to the next page, which is a continuation of paragraph 53.
BY MS. PETERSON:
Q. So right at the top of this page, you

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state that, "Determination of adequate perm ability is a term of degree"; right?
A. Yes.
Q. And that in turn is going to depend on the desired efficacy?
A. Yes.
Q. And the desired efficacy could also depend on the nature of the harmful particles to be captured by the formulation and infection inhibited by?
A. Yes.
Q. That was a bad sentence.
A. I know. I'm not correcting your grammar. But just for clarification, my understanding, again, it depends on, in a microbiological standpoint, the type of organism, the quantity of organism that a person would be coming in contact with.
So you are assuming that you have this capacity to trap -- and I think that's one of the reasons why one of the -- one of the reasons why they decided to change it from "preventing" to the term "inhibiting" so that it's to trap a quantity of harmful bacteria, you know, as best as you can so that you reduce that tighter load that might

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be -- that the individual who would be classified as the host would be experiencing.
Q. And so, of course, you know, the particular nature of the particles will have an impact on how many need to be held by the impermeable thin film in order to prevent infection; right?
A. That's correct. And that ties in with my statement previously regarding the stickiness or the tackiness of that material. It's very important. Because you don't want these particles to be bouncing off and going into the nasal passage, at least that's how I understand the concept.
Q. Okay. So if one were to design a formulation that has, you know, reasonable adhesion and cohesion and creates a thin film of reasonable impermeability, that might be enough to prevent infection by, you know, some microorganism that's not particularly harmful or where the tighter or the amount in the environment is relatively low; right?
A. Yes, I think the example would be during pollen season when you have high pollen counts. Whether you have a pollen sensitivity or not, we

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all tend to sneeze a little bit more during those periods of time. It's because the levels are very high. But throughout the year, we're exposed to pollens, and it may not give us any degree of eye irritation or nasal irritation causing us to sneeze.
Q. Okay. And so using that example then, if we're in allergy season where there's a high amount of allergens in the air, you might need a formulation that has increased adhesive and cohesive properties with a more impermeable barrier in order to sufficiently capture and hold those particles and preventing them from -- or inhibiting them from infecting the individual; right?
A. Or you may want to apply the product more frequently. So I --
Q. And that would be because the adhesive properties would impact how long the formulation stays as a thin film?
A. Well, how long it's going -- well, how much you're coming in contact with -- you know, some people come in contact with very polluted environments, but on an average basis -- again, this is not a prescription, but on an average

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basis a product that you have sold over-the-counter is something that's left up to the individual to make a judgment as far as how much and how often they use the product.
As I said earlier, in my own personal experience of using the product, I use it when I'm in a setting where I do have individuals who are unknown to me. So if I get on a bus, I'm definitely going to use this product.
Q. Okay. And then from the formulator perspective, how does the formulator determine what the desired level of permeability is?
A. The formulator would make that judgment on the -- as I said earlier, the degree of stickiness or tackiness of the actual product. So, again, you would probably conduct experiments to do that.
In this particular case, the process was tested on the basis of the electrostatic surface charge so that if the levels were there to adequately meet a standard that they are claiming that the product can do to attract these particles, you would have that as your -- at least in part, your substantiation that you set up that field.

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Q. Okay. Isn't it also your opinion that the electrostatic field that is generated alone is not sufficient to meet the claim elements of capturing and holding?
A. The electrostatic --
MR. KREMEN: Objection to the form of the question.
THE WITNESS: You may want to rephrase that for me.
BY MS. PETERSON:
Q. Isn't it also your opinion that the electrostatic field that's generated from the formulation, that alone is not sufficient to achieve the claim elements of capturing and holding?
MR. KREMEN: Same objection.
THE WITNESS: And my answer is no. The electrostatic field is -- or the electrostatic charge that's set up is an important element of how this product works. That's the methodology.
BY MS. PETERSON:
Q. Okay. And how does that relate, then, to everything you were just discussing here about the need to have adequate adhesion and cohesion and impermeability to the thin film?

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A. They all tie in, because the charge is generated by those ingredients that's setting up that impermeable setting. You don't want it to bypass it. You want it to hold on to those contaminants, be it biological or otherwise, so that the person does not inhale large quantities. And you want to do that outside of the respiratory track, per se.
Q. Okay. So I asked you earlier how does -- from a formulator perspective, how do they achieve the desired permeability and you referred to the adhesive and cohesive properties of the formulation.
Do you recall that?
A. Yes.
Q. And how does the formulator -- oh, sorry, strike that.
Those adhesive and cohesive properties can be different depending on the ingredients and the percentages of ingredients used in the formulation; right?
A. Yes.
Q. So how does the formulator decide how adhesive it needs to be?
A. Well, that's the testing that would be done. And I think the testing for the properties that we're looking at relate back to the type of surface charge that the product possesses. So you're looking for -- as I'm speaking I'm shaking the monitor here, I'm sorry.
What you're doing is you're looking essentially to set up that field where you're setting up that barrier.
Q. Right. So --
A. And you're measuring that electrostatic charge. Because, again, you're looking at positive and negative particles that have to be trapped -- or negative particles that are in the airstream that have to be trapped by the positive field that's set up on that barrier.
So, you know, you could look at it in different ways. You could look at it from its chemistry, but you could also look at it from the physics of it, which is more related to that electrostatic charge.
Q. So when you say these concepts are related, does that mean that you could have a lower level of adhesion and cohesion in the formulation as long as the formulation exhibits a high electrostatic charge?

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MR. KREMEN: Objection to the form of the question.
THE WITNESS: Can I answer?
MR. KREMEN: Yeah, you can answer.
THE WITNESS: I mean, I feel that, again, the amounts -- the amounts -- what has to be provided is that you are able to set up that impermeable field, that it has to be adequately supplied. So, for example, if I simply take my finger and touch, you know, the product and just put it at the tip of my nose, I won't probably get the same kind of effect as taking the product, putting an adequate amount and spreading it around the whole surface of the nose and maybe putting a little bit in the nostrils to give me that much more barrier of protection.
BY MS. PETERSON:
Q. So the -- to achieve the adequate impermeability recited in the claims, that's also going to depend on how the product is applied by the user?
A. I would assume so, yes.
Q. Okay.
A. But, again, a lot of that is tied in with any of the materials that are supplied --

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excuse me, any of the materials that are supplied with the product. So in my experience, when a product has to be taken by mouth, you have to tell the person, take by mouth because you don't know how that person is going to utilize that product.

Q. Okay. So you're talking about instructions that are provided with a commercial product?

A. That's correct.

Q. You're not talking about instructions that are provided in the '802 patent; right?

A. Not in the patent; correct.

Q. Okay. And what does the patent say about what the desired level of impermeability is for inhibiting infection caused by influenza virus?

A. I don't remember exactly if it states that. So I'm at a disadvantage to respond to that question right now.

Q. So you're not aware of anything in the '802 patent that identifies what the appropriate level of permeability is for inhibiting infection for any of the specific organisms or diseases that are listed in the patent; right?

MR. KREMEN: Objection to form.

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THE WITNESS: I don't think that was necessary at the time that the patent was written. It's simply presenting the concept of how this thing should work, but not -- there's no efficacy data, at least in my understanding, that would be required to incorporate into the patent.

BY MS. PETERSON:

Q. Okay. Well, putting aside whether it's required or not, you didn't see anything like that in the patent; right?

A. Not to my recollection.

Q. No recommendations or instructions as to the level of impermeability that's required for particular harmful properties?

A. At this point, I probably -- I don't recall if it is there. I may have read it, and I just don't remember. I'm sorry.

Q. I didn't see it. I just want to make sure that there isn't something that I was missing. And it sounds like there wasn't?

MR. KREMEN: Objection.

THE WITNESS: I think I've read, you know, the patent a number of times to feel comfortable with it before I speak to you or anybody else about it. But I can't remember at this point if there is.

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BY MS. PETERSON:

Q. Okay. So that's your answer, you don't remember?

A. I don't remember.

Q. Okay.

MS. PETERSON: Let's go to the next page.

BY MS. PETERSON:

Q. And for reference, this is a continuation of paragraph 55 of your declaration. Here, you're talking about the claim term "renders said particulate matter harmless"; right?

A. Yes.

Q. This is a long paragraph, but do you see in the middle of the screen here there's a sentence that says -- it starts "Further" and then it says (at 3 -- that's Column 3, line 12 of the patent.

Do you see that?

A. Yes.

Q. Okay. So you're referring to Column 3, line 12 of the patent specification here. And you quote a sentence that includes the language "simultaneously inactivate, kill, or render

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harmless the microorganisms so trapped."

Do you see that?

A. Yes.

Q. And then you go on to say that, "The significance of this statement is the correlative conjunction 'or'"?

A. Yes.

Q. What's the significant of "or" to you here?

A. Well, my interpretation is that the benzalkonium chloride as the biocide should kill the live organism or render it unavailable to the host, render harmless -- or render harmless, meaning if you have something that's not something to be virulent but it can be irritant, that's what I'm referring to.

So you could have -- as I mentioned earlier, you could have exposure to particles in smoke-filled air. You could have particles that are classified as pollutants or xenobiotics, and they do not necessarily pose a serious health threat to the host, but they could be rendered harmless by being neutralized by that electrostatic charge that's on that membrane or as a result of using the product around the nose.

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Q. So rendered harmless, in your understanding then, can mean either inactivation or killing?
A. More so trapping, trapping them so that -- if it's not a viable material, why would you want to kill it? You want to trap it. You want to stop it from going into or prevent it somehow from going into the nasal passages. Inhibiting is going to slow things down. Preventing is pretty much going to stop it.
So I think what you want to do is you could come in contact with the pollen at a lower concentration and maybe the result of that will be simply to sneeze, but you're not going to have a severe allergic reaction. So it renders it harmless. That's how I understood it.
Q. Okay. I'm not sure I followed all of that. So render harmless, it means trapped?
A. I see that more as trapping it, yes.
Q. Okay.
A. Stopping it outside of the nasal cavity.
Q. Okay. And that trapping relates to the electrostatic attraction?
A. Correct.
Q. Okay.

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A. Or that electrostatic charge that's set up as the barrier. Because if you look at it as a wall of positive charge, anything that's going to pass towards that wall that's set up is going to stick to it.
Q. Okay. Now, you also looked at the prosecution history of the '802 patent; right?
A. Yes.
Q. Okay. And you recall that the claim terms were changed from "preventing" to "inhibiting"; right?
A. Yes.
Q. And the examiner's rationale was that preventing implies that all harmful particulate matter is captured --
A. Yes.
Q. -- as opposed to inhibiting, which could allow some of the harmful particulate matter through?
A. Yes.
Q. Okay. Would you agree that something that's very toxic or, you know, extremely virulent, like anthrax, if even a small amount gets through, that that would not be rendering it harmless?

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A. No, that could be -- I would consider that to be an extreme microorganism where large numbers of those spores could potentially be very detrimental to a person coming in contact with that.
Q. Okay. But --
A. No, I'm sorry. No, that's fine. You can go forward.
Q. Okay. But there are some microorganisms where even if only a few of the organisms make it into the body, that will be sufficient to cause infection in that individual?
A. Yes, that can happen, yes.
Q. Let's move forward to -- one more page, I think it's the last page of your declaration.
A. Okay.
Q. And here in paragraph 56, you're talking about how patent claims are often incomprehensible by laypersons; right?
A. Yes.
Q. But you here are offering the opinion that in the case of Claims 1, 2, 6, and 7 of the '802 patent, the words appear to have their plain meaning; right?
A. Yes.

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Q. Okay. So you would agree that the claim terms as used in the Claims 1, 2, 6, and 7 of the '802 patent just use their plain and ordinary meaning as understood by a person of skill in the art?
A. By a person of ordinary --
MR. KREMEN: Objection to form.
THE WITNESS: Can I answer?
MR. KREMEN: Yeah, go ahead.
THE WITNESS: I felt that a person of ordinary skill reading the claim -- and, again, going back to my example of a student in high school understanding basic physics and positive and negative charges would be able to navigate those statements.
In my experience reading patents, some of the patent claims are extremely written for a person of very high-level understanding. And it prohibits that average layperson to pick that up and be able to interpret what is recited in the body of the patent, as well as in the specific claims.
BY MS. PETERSON:
Q. Okay. But that's not what you understand to be the case for the '802 patent

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claims; right?
A. I understand that the '802 patent claims are written in language that should be understood by a person of ordinary skill.
Q. Okay. So there's no particular essential meaning to any of the particular claims apart from what a person of ordinary skill in the art would understand to be their plain and ordinary meaning?
MR. KREMEN: Objection.
THE WITNESS: To be perfectly honest, I looked at that patent, and I see a very simple concept being presented with a simple solution so that a person of ordinary skill should be able to read that and have some degree of understanding of what's in those claims.
MS. PETERSON: Okay. I'm at a good stopping point right now. Let's go off the record.
THE WITNESS: Okay.
THE VIDEOGRAPHER: We're going off the record. The time is now 3 p.m.
(Recess from the record.)
THE VIDEOGRAPHER: We're back on the record. The time is now 3:12 p.m.

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BY MS. PETERSON:
Q. Dr. Lemmo, I'll ask you again, have you discussed the substance of your deposition testimony with anybody during any of the breaks that we've taken today?
A. No, I did not.
Q. Okay. Thank you.
Okay. I'd like to turn back to your responsive report.
MS. PETERSON: We can pull that up. It's Exhibit 14.
MR. KREMEN: 14. Responsive report on validity.
BY MS. PETERSON:
Q. So, Dr. Lemmo, I did not see a separate list of materials that you reviewed in connection with preparing this report; is that right?
A. That's correct. Anything, if I had additional materials, would have been submitted.
Q. Okay. So would it be fair to say, then, that everything you reviewed or considered in forming the opinions expressed in your responsive report would have been cited directly in your report?
A. Yes.

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Q. Okay. And you're not aware of anything else any other documents or information that you reviewed in forming your opinions that aren't mentioned in the report?
A. I'm sorry, I was just distracted by something. Just please repeat the question, I'm sorry.
Q. You're not aware of anything else, any other documents or other information that you reviewed in forming your opinions that aren't specifically mentioned in the report?
A. No. No, there's nothing else.
Q. Okay. And I think we established this earlier, this report was prepared in response to Dr. Amiji's opening expert report on invalidity; correct?
A. That's correct.
Q. Okay. And other than your opinion directed to the enablement of the Rolf patent application, your report does not provide any other opinions with respect to any of the other prior art identified and relied upon by Dr. Amiji; right?
A. That's correct.
Q. And with respect to the Rolf patent

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application, your report does not provide any opinions with respect to whether the claims of the '802 patent would be obvious in view of Rolf in combination with any other prior art; right?
A. That's correct.
Q. Okay.
MS. PETERSON: Let's turn to page 6, which is page 7 of the PDF.
BY MS. PETERSON:
Q. And this is the section of your opinion relating to the "hold" function; right?
A. Yes.
Q. Okay. So looking at the second sentence, your opinion is that the claimed invention uses electrostatic forces to attract particulate matter before entering the nasal passageway; right?
A. That's correct.
Q. But that's --
MR. KREMEN: That's -- you're misquoting. Before entering the body's respiratory system.
MS. PETERSON: Okay.
BY MS. PETERSON:
Q. Well, looking at the beginning of the

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sentence, it states that "the product attracts particulate matter from the airflow before entering the nasal passageway using [sic] electrostatic forces"; correct?

A. That's correct. And the nasal passage is considered physiologically a part of the respiratory system.

Q. Okay. Now, you go on to then say, though, that "this alone in insufficient to protect the individual from harmful particulate matter entering the body's respiratory system"; right?

A. That's correct.

Q. Okay. So the electrostatic force created by the formulation alone does not protect the individual from harmful particulate matter entering the body, and likewise would not protect that individual or inhibit infection from those materials; right?

MR. KREMEN: Objection to form.

You may answer.

THE WITNESS: The electrostatic charge addresses the negatively charged particles that are in the airflow, but it does not address anything else. So if particles in the airflow are

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negatively charged, the positive charge of the product is going to be a significant player.

I think my point in this paragraph is the importance of the "hold" function. You don't want particles to be bouncing off that surface where the product had been applied and then picked up into the nasal passage.

BY MS. PETERSON:

Q. Okay.

A. So hold -- I keep going back to that "hold" function because it's inhibiting them from going into that respiratory system.

Q. Okay. So, in other words, the electrostatic charge of the formulation alone is not sufficient for a product to function, according to the claim. It also requires this "hold" function that's recited in the claim, as well; right?

A. Yes. I would agree with that, yes.

Q. Okay. And that "hold" function -- we've covered this repeatedly, but it's related to those adhesive and cohesive properties of the formulation and the permeability of the film upon application of the formulation; correct?

A. Exactly, yes.

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Q. Okay. So a formulation that exhibits an electrostatic charge upon application to the skin might not necessarily have the right amount of adhesion or cohesion to perform that "hold" function of the claims; right?

A. That's correct.

MR. KREMEN: Objection to form.

BY MS. PETERSON:

Q. So, in other words, a formulation or a composition would need more than just a positive charge to meet Claims 1 and 2 of the '802 patent?

A. Well, you want the material to adhere, or you want it to remain being held by the material that you're applying to the skin. And that's what I see as an important thing. Just having the electrostatic charge without the ability to hold the product, an electrostatic field could either repel or attract different things. And that's -- you know, that's one aspect of it.

I think the other part is really -- or what I consider to be an extremely important part is that "hold" function, and that's why I probably was more focused at the time that I wrote this document.

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Q. So let me just see if I can repeat that because I just want to make sure I have an answer to my question.

So a formulation that exhibits an electrostatic charge upon the application to the skin might not necessarily have the right amount of adhesion or cohesion to perform that hold function, which is also a necessary component of the claims; right?

A. Yes, that's correct.

Q. Okay. Let's move ahead to -- I think it's page 9 of your report. It's page 10 of the PDF. And this is the section where you discuss the Rolf patent application; correct?

A. Yes, that's correct.

MR. KREMEN: That's the -- where it says paragraph 3, "The Rolf Patent Application"?

MS. PETERSON: Yeah, I'm not sure if it's a paragraph or a section heading, but yes.

MR. KREMEN: Yeah, right.

MS. PETERSON: "3, Rolf Patent Application, that's where we are.

BY MS. PETERSON:

Q. Okay. You understand that essential oils are cationic; right?

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A. That's correct.
Q. Okay. And so when essential oils are applied to the skin, they will exhibit a surface electrostatic charge?
A. That's correct.
Q. Okay. On the next page, if we scroll down, the first full paragraph, you note that there are some "limitations associated with the use of essential oils"; right?
A. Yes, that's correct.
Q. So they may have skin irritating properties?
A. Correct.
Q. Or severe toxicity profiles?
A. Correct.
Q. And that would depend on the amount that is used of the essential oil; right?
A. That would be one component, yes.
Q. And that would also depend on the concentration of the essential oil within the product; right?
A. Correct.
Q. So not all essential oils in all concentrations and in all amounts will cause skin irritation; right?

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A. Correct.
Q. And not all essential oils in all concentrations and in all amounts will be toxic either; right?
A. That's correct.
Q. Okay. So in the second sentence here you refer to reports in the literature.
A. Yes.
Q. Do you see that?
A. Yes.
Q. What literature are you referring to?
MR. KREMEN: Where are you referring to?
THE WITNESS: Second paragraph. Line 2, second paragraph.
MR. KREMEN: Starting with "While the patent application suggests a mechanism"?
THE WITNESS: No, above that.
MR. KREMEN: Okay.
BY MS. PETERSON:
Q. So what literature are you referring to here?
A. A number of -- I did not specify in this document the literature that I referred to on essential oil. Because in the natural products industry, essential oils are employed in a variety

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of applications, particularly for therapeutic -- excuse me, their therapeutic uses. One of the problems associated with essential oils -- I've got something in my throat.
One of the problems associated with essential oil is that essential oils need to be standardized. That indicates the fact that a standardized essential oil is derived from the same part of the plant. It's a seasonal variation component. Its chemistry may change, and there could be also some changes in its relative ratios to other components within that plant.
So for that reason some of these products or some of these oils, like limonene, for example, can present itself as a very useful item in something like a hand sanitizer, but not necessarily a useful item when applied to the skin.
When I read the Rolf patent, I took into consideration reports that I've reviewed or papers that have been written on the subject matter, I did not spell them out but just wanted to call the attention to anybody who would read my report to the fact that there is documented evidence for irritating properties.

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Q. Okay. My question was just a little bit more basic. The literature that you are referring to, it's not cited in your report; right?
A. That's correct.
Q. So we have no way of knowing what essential oils are being discussed under what context; right?
A. That's correct.
Q. Okay.
A. That's correct.
Q. And were these reports in the literature something that you reviewed in connection with forming your opinions, or are these just things that you remember reading over the course of your career?
A. I think it's a combination of both.
Q. Okay. So there are some literature references that you reviewed when performing -- or when forming your opinions and writing this report that are not actually identified here?
A. That's correct. That's correct.
Q. Okay. And I assume that those reports that you're referring to in the literature, those were to specific essential oils as opposed to general statements about all essential oils;

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right?
A. Yes, that's correct. Because many essential oils are used in cosmetic agents, as well. And they're applied to the skin. So they're not irritating at the levels that they are recommended.
Q. Yeah. And I would assume that if they're used in cosmetics, they would be applied to skin on the face --
A. Yes.
Q. -- near the nose?
A. Yes, or wherever. But, yes, you're absolutely right. And if they're used in a soap, you're applying it all over the body.
Q. Okay. Would you agree that whether a particular ingredient exhibits an electrostatic charge that's an inherent feature or property of that ingredient?
A. Yes.
Q. And the '802 patent claimed invention is relying on that inherent feature of those ingredients that have positive charges; correct?
A. That's correct.
Q. And you read the Rolf patent application; right?

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A. Yes, I did.
Q. And you understand that Rolf explains that the formulations it discloses have biocidic properties; right?
A. Yes. Yes, I have.
Q. Yes, you understand that Rolf discloses that its formulations have biocidic properties?
A. Yes, that's correct.
Q. Okay. And those formulations disclosed in Rolf, Rolf explains that they can be used for the prevention of diseases associated with airborne pathogens and respiratory tract pathogens?
A. Yes.
MR. KREMEN: Objection to form.
BY MS. PETERSON:
Q. And it's also your understanding that Rolf explains that these airborne pathogens and respiratory tract pathogens are inactivated upon contact with the essential oil?
A. Yes.
Q. And you also understand that Rolf discloses the use of additional ingredients in its formulation, including antimicrobial agents such as benzalkonium chloride?

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A. Yes.
Q. Now, looking at -- let's skip ahead two pages to the last paragraph of your section on Rolf. So this would be page 12 of the PDF. Okay. So --
MS. PETERSON: Can you go up a little bit? That's great.
BY MS. PETERSON:
Q. So you also offer the opinion that the patch described in Rolf would not function as described in that application; right?
A. That's correct.
Q. Okay. And so that would be your opinion that the Rolf patent application is not enabled?
A. Yes, that's my conclusion. I felt that it wasn't really -- the way it's presented, that the claims really would not work as they're stated.
Q. Okay. So your opinion is based on the conclusion that the claims of Rolf would not work?
MR. KREMEN: Objection to form.
THE WITNESS: The fact that he's using essential oils as the primary component, I just felt in my review of the patent that it really wasn't -- I didn't think of it as really a quality

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scientific proposal in the patent.
BY MS. PETERSON:
Q. Okay.
A. And so I kind of discredited the Rolf patent as a useful argument against the '802 patent.
Q. Okay. And so the basis for your opinion, then, is centered on the fact that it uses essential oils; is that right?
MR. KREMEN: Objection to form.
THE WITNESS: It's a questionable application and a questionable theory that's being presented. And some of the points of the essential oil, as I mentioned before, has to do with standardization of those oils. You may see it sometimes. You may not always. So I didn't feel that it provided adequate foundation.
BY MS. PETERSON:
Q. Do you dispute Rolf's point that essential oils can be used to inactivate airborne pathogens and respiratory tract pathogens?
MR. KREMEN: Objection to the form.
THE WITNESS: Only on the basis that it's cationic in nature. So it's providing a positive charge. There's no reference in Rolf to

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the whole concept of holding. There's no holding mentioned in Rolf. And that, as I go back to my previous statements, was an important aspect of the '802 patent.
BY MS. PETERSON:
Q. Okay. But you do agree that the essential oils in Rolf are cationic and therefore would exhibit an electrostatic charge; right?
A. Yes.
Q. And you testified earlier that that concept is related to the holding concept; right?
MR. KREMEN: Objection.
THE WITNESS: It is related, but there's more to that.
BY MS. PETERSON:
Q. Okay. Now, the adhesive -- the level of adhesion and the level of cohesion provided by a formulation, those would also be inherent properties of a particular formulation; right?
A. Correct.
Q. Okay.
MR. KREMEN: Liane, are we still speaking about Rolf?
MS. PETERSON: Yeah.
MR. KREMEN: Okay.

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MS. PETERSON: We're discussing Rolf.
MR. KREMEN: Okay.
MS. PETERSON: But also generally asking to confirm his understanding of some of the points we've discussed.
MR. KREMEN: Okay. I just wanted to make sure that we had some context.
BY MS. PETERSON:
Q. So, Dr. Lemmo, then is it correct to understand that you don't have any issue with Rolf using -- or applying the formulation through a device, like a patch?
A. No, I have no objection to that.
Q. Okay. The last section of your responsive report relates to commercial success. Do you see that heading, No. 4?
A. Yes.
Q. What standard did you use when determining whether Trutek's products demonstrate commercial success as being relevant to the question of nonobviousness?
A. Well, I felt that commercial success was based upon the number of units that the product was -- that the product has been sold. I use that. I'm trying to understand the relationship

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that you bring up for nonobviousness.
Q. Okay. Let me -- I can break that down for you a little bit better.
A. Yeah, it would be helpful.
Q. Okay. So you say right here in the first sentence that, "I understand that commercial success of a patented product tends to show that the patented claims are not obvious provided that the commercial success is due solely to the patented claims."
Do you see that?
A. Right. Yes.
Q. So is that the standard that you applied in your analysis?
A. Right. In other words, what I was trying to say here, if in the '802 patent, if it doesn't do what they say it's doing, you won't have 7 million sales worldwide or whatever that number is domestically, et cetera. People would not be using the product. It doesn't work. So that contributes to the fact that it is a novel invention, because it's continuously being used and continues to be sold.
Q. Now, you would agree that there could be non-patented features of a product that drive

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demand for the product; right?
A. Sure.
Q. Did you consider whether any non-patented features of Trutek's products contributed to its sales?
MR. KREMEN: Objection to form.
THE WITNESS: I don't know what those might be.
BY MS. PETERSON:
Q. Okay. So that answer is no, I guess?
A. If you could give me -- no, the reason why I say that is, you know, if you could give me an example of what you're referring to, I might be able to give you an opinion.
Q. I don't have a specific example, I'm just asking you if you considered whether there is a possibility that non-patented features of Trutek's product could drive the demand for the product?
A. It's possible.
MR. KREMEN: Objection.
BY MS. PETERSON:
Q. And you did not consider that in your analysis; right?
A. No.

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Q. Okay. Now, this statement in the first sentence of Section 4, where did you obtain that understanding from?
A. I don't remember exactly that. As I said, my thought process for the concept -- the novel concept. I tried to tie that in with my understanding of what happens with products on the market. That was my thinking at the time that I wrote this.
Q. Okay. Now, in the next sentence, you refer to, "Since the time the '802 patent was issued in 2012, approximately seven million units of the product based on this patent, have been sold in the United States and internationally."
Do you see that?
A. Yes.
Q. What product are you referring to?
A. I'm referring to the nasal ointment, the gel that was used.
Q. So I'm sorry, is this NasalGuard?
A. NasalGuard, yes.
Q. Okay. And is it all iterations of NasalGuard or just one specific NasalGuard product?
A. I had -- I generated that piece of

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information as a result of asking Mr. Wahi.
Q. Okay. So Mr. Wahi provided you with information about how many units of a particular NasalGuard product had been sold in the United States?
A. And internationally.
MR. KREMEN: Objection.
BY MS. PETERSON:
Q. And do you know why -- or did you only ask for information on sales for that one specific product?
MR. KREMEN: Objection.
THE WITNESS: Yes.
BY MS. PETERSON:
Q. Why did you only ask for that one product?
A. Because I wanted to just understand how much of the product is being sold. It was for my own knowledge that the product has repeat sales. In the document, I believe I go on to talk about repeat sales of a unit.
Q. Okay.
A. And that's how I was educated on commercial success of a product.
Q. Okay.

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A. As a result --
Q. Okay. So repeat sales --
A. I'm sorry, so repeat sales is a measure -- as I've been educated in the corporate setting, repeat sales of a unit is a measure of the product's success. And that's what keeps it novel.
Q. Okay. So repeat sales is a factor that you considered with respect to commercial success; correct?
A. Yes, that's correct.
Q. And your understanding that repeat sales is relevant comes from your corporate experience?
A. Yes, I relied on that in making my statements.
Q. Okay.
A. And in order to do that -- in order for me to do that, because I can't find that sales data or anything, I had to go back to Trutek and find out from them -- I had to find out from them, you know, what are you selling? How much do you sell? Do you sell 500 units in 12 years or whatever the period of time was? I have to get some sense of how successful this is.
Q. Okay. And going back, you said that you

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asked for information on one specific NasalGuard product because of the fact of these repeat sales; right?
A. That's correct.
MR. KREMEN: Objection to form.
BY MS. PETERSON:
Q. So does that mean that Trutek's other NasalGuard products don't have repeat sales?
A. I don't know. I would assume that they do.
Q. So how did you know that this particular NasalGuard product had repeat sales?
A. I did not know that before I asked Mr. Wahi for the number of sales of the product he has.
Q. So --
A. I don't have sales data or marketing information at my fingerprints.
Q. Okay. So Mr. Wahi provided you with the information about the one particular NasalGuard product that had repeat sales?
MR. KREMEN: Objection.
THE WITNESS: That was one that I asked about. I didn't ask about any other product.

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BY MS. PETERSON:
Q. And going back to that again, why did you only ask about that one product?
A. Because that's the product that I use.
Q. Okay. So do you know anything about the sales of any of the other Trutek NasalGuard products?
A. No, I don't.
Q. So you have no idea if they're being sold at the same levels?
A. I don't know.
Q. But it is your understanding that all of the NasalGuard products have the same exact formulation, with the exception of the scented product which includes an additional ingredient providing that scent; that's correct?
A. That's the way I understand it.
MR. KREMEN: Objection.
BY MS. PETERSON:
Q. Okay. Let's go to the next page.
In the first paragraph, the second full sentence, you also explain that -- it looks like you're explaining another factor you considered, which is that, "Patent protection offers additional support for a product to be considered

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as a success," right?
A. Yes.
Q. Okay. So it's your opinion that part of the success of Trutek's NasalGuard product is the result of it having patent protection?
A. Yes.
Q. And when you refer to patent protection, I assume you're talking about all of Trutek's patents?
A. Just the '802 patent.
Q. You've reviewed Trutek's other patents; correct?
A. Correct.
Q. Do those other patents read on -- or do those other patents cover the Trutek products?
A. I primarily focused on the '802 patent.
Q. Okay. So you aren't sure one way or the other whether any of Trutek's other patents cover the Trutek NasalGuard products?
MR. KREMEN: Objection.
THE WITNESS: As I said previously, I focused primarily on the '802 patent.
BY MS. PETERSON:
Q. I mean, did you look at Trutek's other patents?

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A. Yes.
Q. But you're not sure whether those other Trutek patents that you reviewed cover the NasalGuard products?
MR. KREMEN: That's not what he said.
BY MS. PETERSON:
Q. Can you answer, please?
A. Just repeat the question, I'm sorry.
Q. Okay. You did look at Trutek's other patents; correct?
A. Yes. Yes, I did.
Q. Okay. And you said you focused primarily on the '802 patent?
A. Correct. I looked at the '488 patent. I looked at the '481 patent.
Q. And do those --
A. Those are patents that I -- they focused -- one focused mostly on the method. The other one was on the formulation.
Q. And are you talking about the claims of those patents --
A. Yes.
Q. -- or the disclosure of the patent?
A. The claims.
Q. And do the claims of the patent covering

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the formulation, do those read on the Trutek NasalGuard product?
A. It's been a while since I looked at it. I would have to go back and look at it again.
Q. Okay. So as we're sitting here today, you're not the sure either way, whether the claims of the earlier Trutek formulation patent cover the NasalGuard product?
MR. KREMEN: Objection.
THE WITNESS: I would have to refresh my memory and reread.
BY MS. PETERSON:
Q. Okay. Do you know when NasalGuard was first offered for sale in the United States?
A. I believe that was the 2012. It's possible, but I'm not certain. I do post a year.
Q. And when you obtained this information from Mr. Wahi, did he just give you the number 7 million units, or did he give you, like, sales records for that product?
A. No sales records, no.
Q. So he --
A. He just gave me -- he just mentioned it to me.
Q. Okay. So you had a conversation with

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Mr. Wahi, and he told you that the particular NasalGuard product that you use has sold 7 million units sales since 2012?

A. Yes.

Q. Okay. In that same sentence we were just looking at, you also say that because the Trutek products "have been marketed successfully for ten years, this product line stands tall among products in this category."

Do you see that?

A. Yes.

Q. And here, now it looks like you're talking about the entire Trutek NasalGuard product line?

A. Probably. As I said, to my knowledge, there is an unscented version and a scented version. And that's what I'm referring to.

Q. Okay. So you would agree then that the sales of the Trutek NasalGuard products are due at least in part to their marketing efforts?

MR. KREMEN: Objection.

THE WITNESS: The sales are essentially based on the use by the consumer. So regardless of what their marketing efforts may be, even if they don't do anything -- and they don't really.

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I don't see much advertising for the product, to be honest. But the sales of the product are really based upon, as I said before, repeat sales. If I buy the product, I buy a tube of the product, and I find that I'm -- I like the use of the product and I feel comfortable using the product, I would go out and buy it again.

BY MS. PETERSON:

Q. When did you first start using NasalGuard?

A. The first time that I used it was when we had discussion related to Matrixx Initiatives.

Q. So you were not using NasalGuard prior to being contacted by Trutek.

A. I had no idea of the product.

Q. Would you also agree that the sales of a product can depend, at least in part, on where those products are being sold?

A. Yes.

Q. So certainly, like, a sale on Amazon where consumers can identify the product by searching, you know, that would be easier for a consumer to purchase than if it was only available through a distributor?

MR. KREMEN: Objection.

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THE WITNESS: That is one good example. I could tell you from personal experience products that I've developed sell sometimes better in a foreign country because of the nature of the product as opposed to domestically.

BY MS. PETERSON:

Q. Okay. So the next sentence says that, "The product has a domestic and international presence which demonstrates that it has been reviewed for human use without prescription for the claimed properties established in the patent."

A. Yes.

Q. Can you explain what you mean by that?

A. Okay. When a product is placed on the market domestically and you make claims for the product, the claims have to be substantiated and usually submitted to one of the regulatory bodies. Within a corporation, you have an internal regulatory body who reviews the product and reviews the claims that you're making about the product and affirms the fact that what you're saying about the product will, in fact, do what you state on your labeling.

Q. Okay. So those are all related to statements made in the labeling for a product or

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in the advertisement for a product; correct?

A. Correct. And it relates primarily to the regulatory affairs department.

Q. Okay. So you're not suggesting here that the FDA reviewed information to confirm that NasalGuard practices each and every element of the '802 patent claims; right?

MR. KREMEN: Objection.

THE WITNESS: No, I'm not saying that.

BY MS. PETERSON:

Q. Okay. So, rather, you're talking about the product being reviewed to substantiate claims that Trutek makes in its website or product packaging or product labeling to make sure that they're accurate?

A. If a product is on the market and in violation of the FDA, you would receive an FDA letter, a warning letter, that your product is either misbranded or mislabeled. And to my knowledge, that doesn't exist. Otherwise, that product would be off the market at this point. No retailer would carry that product.

Q. Sure. Okay.

Now, at the bottom of this page, you talk a little bit how the Trutek NasalGuard

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products operate.
A. The page has to be raised. I'm not seeing --
MS. PETERSON: Yeah, can you scroll down a little bit. I'm looking at the last full paragraph. The last paragraph, so starting with "The commercial" -- there we go.
BY MS. PETERSON:
Q. Okay. So you talk about how "The '802 patent claims a product that electrostatically inhibits harmful airborne particles from infecting an individual."
And then you go on to say, "This product effectively prevents that from happening by creating a positive electrostatic charge that attracts the particles and holds the particles in place until a biocide can inactivate them and render them harmless"; correct?
A. That's correct.
Q. So that's your understanding of how NasalGuard operates.
A. That's my understanding of the mechanism, yes.
Q. Okay. So that electrostatic charge both attracts the particles and holds the particles in

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place; correct?
MR. KREMEN: Objection.
THE WITNESS: I think I reiterated the fact that the holding, that cohesive nature, was aside from, that related primarily to that impermeability that was related. There were other ingredients.
BY MS. PETERSON:
Q. But here you're saying that the electrostatic charge attracts the particles and holds the particles in place; correct?
A. Yes. Yes.
Q. Okay.
A. But there are other components to the product.
Q. Okay.
A. For the holding function.
Q. But certainly the electrostatic charge, in your opinion, here with respect to NasalGuard performs both of those functions?
A. Yes.
Q. Okay. Now, you did not do a claim-by-claim analysis of whether the Trutek NasalGuard products practice each and every element of the '802 patent claims; correct?

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A. I did not conduct any of that, no.
Q. Okay. But you did rely on some testing of NasalGuard conducted by Dr. Burns and -- Mr. Burns and Dr. Ermakov; correct?
A. Yes, that's correct.
Q. Okay. And that of course was the testing with respect to the conductivity or the electrostatic charge of the formulation?
A. The electrostatic charge, not the conductivity.
Q. Well, they were testing -- you don't disagree that they were testing the conductivity; right?
A. They were not testing conductivity. They were testing electrostatic charge.
Q. Well, no.
A. Conductivity --
Q. That's what they ultimately reported.
A. Conductivity --
Q. But they were actually --
A. No.
Q. -- measuring --
A. No. My understanding of conductivity is the placement of the electrode into the solution. The electrode -- and that's one of the reasons why

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I wanted to witness this, to go there and see what they did.
Q. Okay. Regardless, the testing that you relied on with respect to whether Trutek products practice the '802 patent claims, that would be the Burns and Ermakov testing about the surface electrostatic charge of the products; correct?
A. That's correct.
Q. Okay. And that's the information that you relied on in forming your opinion that the commercial success of NasalGuard is due to the claimed invention?
MR. KREMEN: Jeez, objection to form.
THE WITNESS: There's a -- the testing demonstrates the fact that there is an electrostatic charge. So the claim that the mechanism utilizing the electrostatic charge is substantiated by the work of Dr. Ermakov as well as Mr. Burns in separate studies using either a piece of paper or a physiologically useful agent, namely, the pigskin that was done by Mr. Burns.
BY MS. PETERSON:
Q. Okay. And you didn't do any other testing of the level of adhesion or cohesion provided by the NasalGuard formulation?

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A. Me personally, no.
Q. And you're not aware of anybody else conducting that testing; correct?
A. I'm not aware of it, that's correct.
Q. And you didn't rely on it; right?
A. I would have mentioned it.
Q. And, similarly, you didn't rely on any testing or -- you did not rely on any testing of the level of permeability of any thin film formed by NasalGuard upon application of the product?
A. No, I did not.
Q. Okay.
MS. PETERSON: Last page, can we turn one more page forward.
BY MS. PETERSON:
Q. You also conclude here that, "The patent number of the '802 patent is clearly marked for every unit sold in the United States."
Do you see that?
A. Yes.
Q. And what's the basis for that assertion?
A. That's for patent protection but that the person -- again, if a person tries to market a similar product without that patent number, that could be a violation, in my opinion.

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Q. Okay. Yeah, no, my question was just how do you know that the patent number of the '802 patent is clearly marked for every unit sold in the United States?
A. Oh, because I use the product.
Q. Okay. So you looked at one of your products, and you saw the patent number listed?
A. Yeah. And, you know, it would be unusual for me to get a product that has a serial number and someone else get it without. That's just part of quality control and quality assurance in the manufacturing sector of a business.
Q. And it's your understanding that there could be potential liability if a company does not include a patent marking on its product?
MR. KREMEN: Objection to form.
THE WITNESS: It's not so much liability. It's more so protection of your product that it is patented.
BY MS. PETERSON:
Q. Now, you only --
A. Because if it --
Q. -- started using NasalGuard in 2020 --
A. Probably it was early 2020. I had some serious illness in 2019, and as a result, I started using the product in 2020. It was in and around the time that we started learning more about coronavirus, and I was looking for ways that I can protect myself in addition to wearing the mask and being vaccinated.
Q. Okay. So you did not use NasalGuard prior to 2020; right?
A. I wasn't familiar with the product, as I stated earlier.
Q. Okay. So you don't know for certain whether the '802 patent was marked on NasalGuard products that were sold prior to 2020; right?
A. No, I don't know that.
Q. Okay.
MS. PETERSON: We can take that exhibit down.
BY MS. PETERSON:
Q. I'd like to take a look at your -- let's mark another exhibit. This is a list of materials that you reviewed that was attached to your opening report.
MS. PETERSON: Jennifer, I think it's item No. 7. It says "Lemmo Materials Reviewed." We'll mark this as Exhibit 17.
(Lemmo Deposition Exhibit 18 was marked for identification and attached to the transcript.)
MR. KREMEN: 18. 17 was --
MS. PETERSON: Oh, yes, 18. Thank you.
BY MS. PETERSON:
Q. Okay. Dr. Lemmo, do you recognize Exhibit 18?
A. Yes.
Q. And this is a list of materials that you reviewed that you prepared and attached to your opening report; correct?
A. That's correct.
Q. Okay. Other than the materials listed here on Exhibit 18, did you review anything else in forming your opinions stated in your opening report?
A. Only the ones that are listed here.
Q. Okay. Did you identify personally each of these -- well, never mind. Strike that.
Okay. Item No. 6 refers to "Information on the NanoBio Protect product packaging."
Do you see that?
A. Yes.
Q. And that would be your own personal copies of the product packaging that you had in

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your possession?
A. Whatever I was able to obtain on the website for NanoBio.
Q. Okay. Item No. 5, copies of the portion of the BlueWillow website.
Do you see that?
A. Yes.
Q. Did you identify those sections of the website yourself personally, or were you provided them or directed to them by counsel?
A. When I was retained by Mr. Wahi and he told me a little bit about the case, routinely in order to familiarize myself, I'll do a quick search in the literature to what I could find out about the company. BlueWillow was not a company that I was familiar with before Mr. Wahi had contacted me at that time.
Q. And I assume that means you weren't familiar with the NanoBio Protect product either?
A. Not at all.
Q. Never came across it?
A. Not at all.
Q. Okay. And, actually, I just realized I mischaracterized something in that list. Item No. 6, I can't remember if I said that that was

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NasalGuard product packaging or NanoBio Protect product packaged. So let me ask you again.
This NanoBio Protect product packaging that you're referring to, is that something you purchased, or was it provided to you?
A. No, it was what I found on the Internet.
Q. Okay.
A. Any image -- what I generally do is I'll search for images of the product, and I'll try to zoom in on the content -- the label content, information that's posted on the label.
Q. Okay.
A. But I never had physically the label in my hands.
Q. Okay. Items No. 7 and 8 contain a list of patents in a published patent application.
Do you see that?
A. Yes.
Q. Why did you review those?
A. They were probably to give me foundation information so that I can evaluate -- I'd have to go back and look at my files -- so that I could evaluate and give a response to the plaintiff as far as what I reviewed. Before I can make a judgment on a thing or give advice to a company,

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be it to Mr. Kremen or Mr. Wahi or any other clients that I may have in the past or in the hopefully future, you know, I provide them with background information that I find. I'll do a patent search.
Q. Okay. So is it your recollection that these patents are directed to different oil-in-water emulsions?
A. It's possible that that's the case. Offhand, I don't have -- I apologize for not listing the patent number and the descriptor on this as a list. But I do have those files.
Q. But they were identified by you and reviewed by you for background purposes?
A. Yes, that's correct.
Q. To further inform you about the products at issue in the case?
A. Yes. Just to familiarize myself with what was going on. It's very difficult, especially when you're looking at a product that you have no knowledge of and claims that are being made, especially for the NanoBio product and what NanoBio was attempting to do with their products -- or rather -- I'm sorry, rather what BlueWillow was attempting to do with their

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products, including the NanoBio Protect product, so that I get a clearer picture of what the entity, what this business was all about.
Q. Okay. And then to the best of your recollection, there wasn't anything specific within any of these patents that you specifically relied on and mentioned in your report; correct?
MR. KREMEN: Objection.
THE WITNESS: Not to my knowledge. I cannot spell it out at this point. Because, again, I need to see what the title of the patent was to clarify it. At this point, looking at patent numbers is kind of like looking at a foreign language for me.
BY MS. PETERSON:
Q. Sure. Okay. And then the rest of the items on your list, it's a number of publications; correct?
A. That's correct.
Q. And what was the purpose for reviewing these?
A. Again, to familiarize myself more so with what nanoemulsions are as well as what nanotechnology involved. Having done the research in terms of what BlueWillow was doing as research,

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not necessarily for the commercial aspect but the research work that they were doing, to better familiarize myself so that I can express myself relative to what the nanotechnology and microemulsions in their applications really meant.

Q. Okay. And these patents and publications, these are general materials relating to nanoemulsion, not necessarily directed to specific research being conducted by BlueWillow; right?

A. Yes, that's correct.

Q. Okay.

A. It was for my own edification so that I would be able to speak about it.

Q. Okay.

MS. PETERSON: We can take that down.

MR. KREMEN: Would it be a good time for a break right now?

MS. PETERSON: Sure. We can go off the record.

THE VIDEOGRAPHER: We're going off the record. The time is now 4:12 p.m.

(Recess from the record.)

THE VIDEOGRAPHER: We're back on the record. The time is now 4:24 p.m.

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MS. PETERSON: Okay. Let's pull up Exhibit 13, which is Dr. Lemmo's opening expert report.

THE REMOTE TECHNICIAN: Stand by.

MS. PETERSON: And this one at least has legible page numbers. So hopefully that will help out. But if we could turn to page 8 of the report, which is page 11 of the PDF.

BY MS. PETERSON:

Q. Okay. So at the top of this page, Section 3, Dr. Lemmo, you included an explanation of nanoemulsion technology, correct?

A. That's correct.

Q. Why did you include this?

A. I wanted to reiterate what I said earlier about those references in that I read -- I read references about the nanoemulsion process, the technology, acting as an interesting delivery system as opposed to a person who was just -- had not pretty much done their homework in reviewing the material. So it was essentially to get a foundation started.

Q. Okay. And you understand that NanoBio Protect is a nanoemulsion product?

A. Yes.

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Q. Okay. So at the bottom of this paragraph, you have a sentence that's underlined where you state that, "By their very nature, nanoemulsion droplets exhibit an electrostatic charge which causes them to repel one-another" --

A. Yes.

Q. -- correct?

A. Yes.

Q. Okay. So when a nanoemulsion is applied to the skin, it exists as individual droplets?

A. Yes.

Q. And then after application to the skin, they remain as separate droplets on the skin --

A. Right.

Q. -- as a result of that electrostatic charge; right?

A. Right. I believe that's the way it is. And they would coalescent to a single liquid mass if they were not electrostatically charged.

Q. So, in other words, when applied to the skin, they don't form a continuous layer on the skin. They still exist as droplets?

A. That is my understanding of how the technology works. Because you have positive and negative charge built into the structure of the

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nanoemulsion.

Q. Okay. Now, you -- we touched on this briefly, but you also relied on reports prepared by Dr. Ermakov and Mr. Burns about some testing that they did --

A. Yes.

Q. -- in forming your opinions as stated in your opening report; correct?

A. Yes, that's correct.

Q. Okay. So on page 9 --

MS. PETERSON: If we can turn to that, please.

If you go down a little bit farther. Okay. The paragraph that starts on January 11th.

BY MS. PETERSON:

Q. About halfway through that paragraph, you state, "I reviewed this report" -- and here we're referring to Dr. Ermakov -- "and found Dr. Ermakov's methodology and conclusions to be sound."

A. Yes, that's correct.

Q. That's your position?

A. Yes.

Q. Okay. And then on the next page, you make the same statement regarding Mr. Burns, as

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well; correct?
A. That's correct.
Q. So you also found Mr. Burns' methodology and conclusions to be sound --
A. Yes.
Q. -- based on what you reviewed in his report?
A. Based on his report, yes. As well as Dr. Ermakov's report.
Q. Okay. And I think we established this earlier, but you did not have any meetings or discussions with Mr. Burns or Dr. Ermakov prior to preparing your report; right?
A. That's correct. I relied solely on the written report.
Q. Okay. So I assume, then, also that you did not participate or make the decision to have Dr. Ermakov and Mr. Burns conduct the testing?
A. I had no involvement in those decisions.
Q. And I also assume you did not identify Dr. Ermakov or Mr. Burns as candidates to oversee and design that testing?
A. That's correct. I did not know either one of them.
Q. Okay. You anticipated my next question.

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So you never worked with either one before?
A. Neither one.
Q. Okay. Not aware of either of them prior to reviewing their reports?
A. Not at all.
MR. KREMEN: Um -- okay. Go ahead.
THE WITNESS: Perhaps -- you know, the only thing that I can say is if they were part of the discussion related to the case against Matrixx Initiatives, it's possible that I read reports if that was employed. But at this point I'm not certain. So I can't commit to that.
BY MS. PETERSON:
Q. So if you were aware of them prior to preparing this opening report, it would have been in connection with them preparing reports of a similar nature for use in the Matrixx?
A. That's correct. Yes, that's correct. But I did not know either one of them. They are complete strangers to me.
Q. So you were not aware of either of them outside of the work on your matter involving BlueWillow or Matrixx?
A. That's correct.
Q. Okay. Now, neither of the reports by

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Dr. Ermakov or Mr. Burns include a CV; correct?
A. That's correct.
Q. Did you -- have you reviewed or -- did you review any résumés or CV for Mr. Burns or Dr. Ermakov --
A. No, I have --
Q. -- prior to preparing your report?
A. No, I never checked on their academic credentials or their employment status.
Q. So you didn't do anything to investigate their qualifications before relying on their testing?
A. No, I did not.
Q. I assume you also did not have any role or participate in designing the test methods used by Dr. Ermakov and Mr. Burns?
A. I had no involvement.
Q. Did you review those test methods or protocols prior to them performing the experiments?
A. No.
Q. And no role in designing the conditions under which the testing occurred?
A. I'm sorry, I missed the beginning of your statement. Can you just repeat that for me?

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Q. You didn't have any role or participate in designing the conditions under which the testing occurred?
A. Oh, no, I had absolutely no involvement with either one of them.
Q. Did you have any role or participate in the decision to decide that the products should be tested on paper and on dried pigskin?
A. No, not at all.
Q. And did you have any role or participate in any discussions about what equipment should be used in the testing?
A. No, no involvement.
Q. It is your understanding that Mr. Burns and Dr. Ermakov used different equipment; correct?
A. Yes.
Q. Do you know why that is?
A. I would -- again, this is an assumption on my part, it's just the manner in which they conduct their tests in their independent laboratories. So how Dr. Ermakov did his testing for surface charge versus how Mr. Burns did his testing using the equipment for the measurements, I had no knowledge of that except for what I read in these reports.

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Q. Okay. So looking then at these statements in -- on pages 9 and 10 of your report, what did you base your conclusion that their methodology was sound?

A. Just on what I read. I assumed that their methodology -- one being in a respected university of which I'm a graduate, I'm assuming that he would utilize methodology that would be sound. Mr. Burns worked for -- I believe it's a private laboratory, outside laboratory. In my past experience, I've used outside laboratories for analytical purposes, and I assume that they have the necessary credentialing and certifications that are afforded to these laboratories to be responsible with the results that they provide.

Q. Okay. So, in other words, to confirm that their methodology was sound, you relied on what they contained in their -- of what they provided in their reports?

A. Yes, that's correct.

Q. And you didn't do any other independent investigation to assess the accuracy of the methodology other than what was written in the reports?

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A. No, I didn't think that it was necessary for me to do so. I took it at face value that it was reliable.

Q. And I don't have the name of his laboratory, but the laboratory that Dr. Burns -- Mr. Burns is associated with, have you ever worked with --

A. ETS. ETS.

Q. ETS. Thank you.

A. Yes.

Q. Have you ever worked with ETS previously?

A. No, not at all.

Q. Had you ever heard of ETS?

A. No.

Q. Do you know what type of testing ETS is typically engaged in?

A. I never investigated it in great detail.

Q. Do you know how often Mr. Burns or Dr. Ermakov performed tests of the nature described in their reports?

A. I did not inquire on that, no.

Q. Do you know if Dr. Burns or -- Mr. Burns or Dr. Ermakov typically conduct this type of testing in the normal course of business?

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A. I don't know the answer to that, but I would assume that they do that routinely only because of what I witnessed their facilities.

Q. And that's something that you learned after preparing your report.

A. That's correct.

Q. Okay. How did you determine that the appropriate equipment was used by Mr. Burns and Dr. Ermakov at the time that you prepared your opening and reply reports on infringement?

A. I relied exclusively on what they wrote.

Q. Okay.

A. So I just -- I pretty much just use that as reference that what they were stating was factual.

Q. Okay. Bear with me for one second.

A. Sure.

Q. Do you know when -- okay. So both Mr. Burns and Dr. Ermakov, they both tested Trutek samples as well BlueWillow NanoBio Protect samples; correct?

A. That's correct.

Q. Do you know when those samples were manufactured?

A. I don't know.

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Q. Do you know what their expiration date was?

A. I don't know.

Q. Do you know what lot numbers the samples were that were tested?

A. I don't think that they were reported in the body of the reports. They may have had coding, but I offhand at this point can't recall.

THE WITNESS: Bless you.

MR. KREMEN: Thank you.

BY MS. PETERSON:

Q. So you don't know if the products -- if they were expired or not at the time of testing?

A. I assumed that they were not, but I don't know that.

Q. Okay. Did Mr. Burns run any standards --

A. In my --

Q. -- over the course of his experiment in order to calibrate the equipment and ensure the accuracy of the test method?

A. Actually, I asked him that question, and the answer is yes.

Q. And is that reflected in his report?

A. I think the reason why I asked him that

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question was I may have been uncertain as far as what was reported in the document itself. So I needed to confirm that based upon my own experience working in a laboratory when I was a graduate student standardizing the equipment that I used on a routine basis. So I simply asked him.

Q. And that's a pretty typical thing that you would expect that the equipment would be standardized using --

A. Yes.

Q. -- a tool with a known value; right?

A. Yes, absolutely. And that's how I was taught. So, you know, you standardize your equipment before you use it. And particularly in a case like this, you really want to have it standardized because you're writing a report regarding a legal matter.

Q. And that information was not contained within Mr. Burns' report; correct?

A. I don't remember. I don't think so.

Q. And that's why you asked him about it at your meeting within the last couple of weeks?

A. Yes. It was just to confirm how they go about standardizing their equipment. And I explained my own experience working in the

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laboratory how I learned to standardize equipment during an instrumentation course as well as during the time that I was in grad school.

Q. So at the time that you formed and prepared your opinions on infringement, you had no way of knowing whether Mr. Burns actually calibrated his equipment with a known standard?

A. I would assume that he did because he works for what I saw as a reliable company. And Dr. Ermakov, being at Rutgers University -- from my experience at Rutgers University as a grad student there, I know that the equipment routinely gets standardized. It's kind of standard procedure when you're in an institution of that nature.

Q. And did Dr. Ermakov's report indicate that he ran any known standards to calibrate the equipment or to ensure the accuracy of the test method?

A. I think when you look at the test results where he's comparing it to a blank substrate and then each of the test features, I think there are three or four more, I needed to understand how he arrived at the conclusions that he reached in his result. So I asked him to

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demonstrate for me to understand how he carried out his test.

Q. Right. And --

A. And I did the same -- I'm sorry. I did the same with Mr. Burns when I visited his facility. I requested just to witness it so that I can again feel more comfortable in having this conversation.

Q. Okay. So, again, that was all after you prepared your reports and formed your --

A. Yes.

Q. -- opinions; right?

A. Yes, that's correct.

Q. So going back to what you said about Dr. Ermakov's report and testing, you mentioned looking at his test results where he compares it to a blank substrate; right?

A. That's correct.

Q. So is that what you're referring to with respect --

A. Yes.

Q. -- to whether Dr. Ermakov -- I mean, that's a control; right?

A. That's a control, yes.

Q. Okay.

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A. But you're talking about standardization of the equipment --

Q. Yeah.

A. -- and the routine standard -- that the equipment is functioning accurately. And that's not reflected in that report, to my knowledge.

Q. Okay.

A. And I don't think he was -- I don't think he needed to indicate that in his -- based upon the nature of his report. It was basically a comparative study. So we assume that everything was standardized. But, again, I can't swear to that.

Q. So you're assuming that everything is standardized because you're just comparing the results between two products?

A. No, I'm assuming that it's all standardized because of the nature in which it was conducted. At Rutgers University, that's a standard protocol for laboratories. It's not -- you know, it's in the chemistry department, and routinely there's quality control and quality assurance and people who will walk around the laboratory making sure that everything is working correctly.

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I also think in a commercial laboratory like ETS that they, too, have guidelines for standardization of their equipment before they run any samples for any clients.

Q. Right. So your expectation was that they would have run standards to calibrate the equipment, but you can't be certain whether or not they did?

A. Yeah, I wasn't there.

Q. Okay. So while we're talking about controls, did Dr. Burns run any controls in his experiment?

A. Yes.

Q. And what were those? What was the control that he ran?

A. I believe it was simply the pigskin by itself in the Faraday cup.

Q. Okay. And does he -- but he doesn't report the results of any testing of the plain pigskin prior to application of the formulations; correct?

A. You know, to be honest, I'd have to look again at the report to see, but I'm assuming the answer is that he did not identify that.

Q. I mean, I know in Dr. Ermakov's report

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he did test the blank paper and reported results?

A. Yes. Yes.

Q. But I did not see that in Mr. Burns. Okay.

A. Yeah, I did not. Yeah.

Q. Okay. Going back to Dr. Ermakov, the control that he used, it was just a plain piece of paper; right?

A. That's correct. I believe it was kind of like a cardboard or that which you would find like an index card of that nature.

Q. Okay. And he was able to detect a surface charge on that substrate; correct?

A. That's correct.

Q. Would you expect to see a surface charge on untreated paper?

A. Yes.

Q. Is paper conductive?

A. I think liquids are more conductive, but I think that surface charge -- particle charge would be on any surface.

Q. Let's -- actually, going back to Mr. Burns, is it your recollection that the controls were not just plain pigskin, but pigskin that had been ionized to neutralize the existing

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charge?

A. That's a question that I would refer you to Mr. Burns, as far as exactly what he did, if he did anything, to the control.

Q. Okay.

A. I'm not -- I'm not comfortable in giving you an answer that I may be misleading you.

Q. Okay. If you were going to measure the surface charge of a product applied to a substrate, would it be important to make sure that that substrate doesn't have a surface charge of its own?

A. The substrate routinely would have a surface charge. And the way in which the experiments were both conducted was to use the substrate with an area of the material being tested where each test sample had its own built-in control so that if there was a surface charge to the paper, in the case of Dr. Ermakov's investigation, that would be reflected as the natural surface charge of the paper by itself, which should be, in fact, equivalent or in very close proximity to the surface charge that was found in the plain paper control.

And when the test material is placed in

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the apparatus and spun under the electrode, the electrode is not on the surface of the test material, but it's above, it basically is going to give a reading that would reflect the fact that half of the test material has no application of the test material, is plain paper, and the other half has got the actual material on it that's being tested.

So it's kind of like acting -- each of the tests are kind of like acting on the basis that you've got the control and the active being incorporated to negate what may be contributed by the substrate.

Q. Okay. Let me make sure I understand that. So you're saying that the way these tests were conducted is that it's not just measuring the surface charge in the location where the formulation is applied, but both in that spot as well as outside where it's just the plain substrate?

A. Yes, because the material is spun under an electrode. So it's acting as a control within the test material itself. So there is a control built in, in that if the surface is going to have a charge, anything you're adding to that surface

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will boost that level of charge because of the charge that's existent on the material itself that you're questioning. So you've got the surface -- the substrate as the surface, and then you have the test sample added to half of that piece of paper in the case of Dr. Ermakov.

Q. Okay. And is this something that you learned from your conversations with Mr. Burns and Dr. Ermakov?

A. It was the result of my visit to ask them to demonstrate it for me. Because this is not something that I have a great deal of experience in, and as a result, I could read the test results and I can understand his conclusion based upon that, but it's very different when you actually witness what the investigator did in the test procedure. Since I had no involvement in requesting the tests or any knowledge whatsoever about the nature of the laboratory that it was done, it was best for me to witness it, and that's what I did.

Q. That's what you did when you met with them earlier this month?

A. Yes.

Q. Okay.

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A. Yes.

Q. Now, both sets of tests, they were conducted at room temperature; correct?

A. I believe so, yes.

Q. And that's lower than what you would expect for human body temperature?

A. Yes.

Q. Now, Mr. Burns used pigskin as a substrate for his testing; right?

A. That's correct.

Q. And at the time that you prepared your report, what did you do to determine whether that was an appropriate substrate for purposes of this test?

A. I simply looked at the literature on the use of either artificial skin or using another example. And my understanding simply from my experience in physiology and my teaching experience, I've been well aware and I've taught about the subject. In the case of valve replacements in hearts, the valves are usually derived from animals such as pig. So it's a suitable physiologically significant tissue to use to demonstrate what would happen in the case of human skin.

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Q. Okay. So you're talking there about an organ like a heart as opposed to specifically human skin; right?

A. Well, if you have to use -- if you have to use an animal model, you really want to have an animal model that is as closely resembling the human in which the agent is going to be tested. I would not be testing, for example, a digestive function of a cow who has a four-compartment stomach and compare that to a human because we only have a one-compartment. So I want to find a molding that is as closely physiologically similar. And I think Mr. Burns made that selection on that basis.

Q. Okay.

A. But that's a question that you'd probably have to pose to him to better explain it.

Q. Yeah. But I'm wondering about what you did to independently confirm that the methodology was sound with respect to the substrate that was selected here. So it sounds like you did some research on your own in the literature?

A. I tried to find as much as I could in order to -- again, if you're asking for an opinion from me, I can't just pull it out of thin air. I

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have to go back and look at references and see what other people may have used in these kind of determinations. And, also, one of my concerns is always is this a standard test? Is this something that routinely if I were going to investigate this as part of my research project, is this the protocol that I would use? That's just my own nature of how I would be investigating things.

Q. Okay. And I have a few follow-up questions there.

So the literature that you researched, that would be the paper that you've cited in your reply report; correct?

A. That's correct.

Q. Okay.

A. Yes, I think the researcher -- I'm not certain -- it has a three-letter word, Abd or Adb. That's the person that I relied on, yes.

Q. Okay. So that was something that you did in connection with forming your opinions in your reply report; right?

A. That's correct. That's correct.

Q. Now, you also mentioned one of your concerns in research projects is whether something is a standard test. Have you ever had the need to

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measure the surface charge of a pharmaceutical formulation over the course of your career?
A. No.
MR. KREMEN: Objection to form.
BY MS. PETERSON:
Q. So the testing that Mr. Burns and Dr. Ermakov did, you've never had occasion to consider such testing or rely on any such testing apart from your work for Trutek in these matters; right?
MR. KREMEN: Objection to the form of the question.
THE WITNESS: Well, I've never had the opportunity to investigate it like that. That was not something that I've ever done.
BY MS. PETERSON:
Q. Okay.
A. So no other client has come to me to investigate surface charge.
Q. Okay.
A. If that's what you want to know.
Q. Okay. And you never did that over the course of your work through the various companies that you've worked with over your career either; right?

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A. No, the only closely resembling activity would have been in my instrumentation and my honor's course in chemistry and measuring ion and absorption to services. That would pretty much be the only connection that I can relate to.
Q. Okay. Now, going back to something else you said, you said it was important to use an animal model that closely resembles or is similar to the intended test subject; correct?
A. That's correct.
Q. Are you aware of the fact that human cadaver skin is also available for testing?
A. Yes. And you could also use artificial skin. So there are options that could be used.
Q. Would you find human skin to be a more accurate reflection of how a surface charge will exhibit upon application of these products to human skin as compared to pigskin?
A. I can't really comment on that accurately. So I would say I'm not really certain. I can make assumptions, but one of the key features is really if, in fact, the skin physiologically is going to be the same. And it's also a question of availability, whether or not that's something that the laboratory would be

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using. I don't know what the restrictions are or the legalities relative to the types of skin that might be employed in a laboratory setting like ETS.
Q. Okay. Do you know what part of the pig the skin samples came from?
A. No, I don't.
Q. Do you know what the physiological differences are between pigskin and human skin?
A. Well, in my reading, it indicates the fact that they are very similar.
Q. Do you know whether there are any differences between pigskin and human skin, particularly within, like, the area of the nostril and nasal passages?
A. I couldn't really comment. I would have to do another investigation as far as cellular composition of the skin.
Q. Now, Dr. Ermakov used paper as a substrate in his testing; right?
A. That's correct.
Q. And did you do anything to independently determine whether paper was an appropriate substrate for purposes of this test?
A. When I reviewed Dr. Ermakov's work, I

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assumed that it was to establish some degree of baseline that, in fact, the test materials would have a surface charge. So regardless of what he used, I think he probably had evidence that paper would be a good substrate, an adequate substrate to conduct this kind of investigation to establish a baseline for surface charge.
I also, when I met with him, asked him if he had done this work previously, and he has. So if he's doing this, he must know that this works appropriately, particularly to establish a baseline. The work by Burns would be a step above the work by Ermakov in establishing it in a more physiological or physiologically similar condition using the pigskin to what you would see in human flesh.
Q. So when you refer to Dr. Ermakov's work as establishing a baseline, you're referring to the fact that it's measuring surface charge but not on a substrate that really is reflective of how the products are going to be used in -- under actual real life conditions?
A. I think that the purpose of his study was simply to establish whether or not there was a charge and how you are comparing those examples.

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So he had to use something. It's similar to what you would do in any kind of experiment. You have to start someplace.

Q. Okay. And then all of that explanation that you just got about Dr. Ermakov, again, that was from your conversation with him a couple of weeks ago?

A. Yes.

Q. That was not information that you were aware of at the time you prepared your reports on infringement; correct?

A. No, that's correct.

Q. So over the course of your career, when you've used equipment to conduct various tests, is it important to run a number of tests to confirm reliability of the method?

A. I'm not following your question when you say --

Q. Well, if you wanted to -- let's say you wanted to measure the surface charge of something. Would it be important to you to run the test in multiple replications so that you can ensure --

A. Oh, yes.

Q. -- the reliability and precision of the method?

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A. Yes, absolutely. Absolutely. And, you know, typically, whenever -- at the time when I was conducting research work at Rutgers University, you know, we would run multiple samples so that we would get an average value, and that average value was then statistically analyzed so that we would have a framework.

But before we would go to the statistical analysis of it, we had to establish some basics that, in fact, what we were doing was appropriate, that we were getting a reading. So we established that baseline.

Q. Okay. And so before relying on the results of that testing, you would run the experiment with a number of replicates, you would determine the average, the standard deviation, and then determine whether those results were statistically significant?

A. Yes.

Q. Okay.

MR. KREMEN: Objection.

THE WITNESS: But that wasn't relevant to what he did.

BY MS. PETERSON:

Q. Now, you recall from reviewing the

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results that for the most part the measurements obtained by Dr. Burns and Ermakov were pretty consistent with each other; right?

A. Yes.

Q. With one exception, do you recall that the results obtained from the measurement by Dr. Burns of the BlueWillow product, that there was actually a pretty wide variation in those results?

A. Yes, that's to be expected.

Q. And why is that to be expected?

A. There could be any number of factors that can contribute to that. But the purpose of the study was just to establish whether or not there was a surface charge.

Q. Okay.

A. It wasn't a -- in doing experimentation, there are different goals, and it's either a quantifiable goal or just the identification goal. And the goal in both of these studies, to my knowledge, was to identify the fact that the samples that were tested, in fact, exerted a surface charge.

Q. So for purposes of your analysis and your opinions, you were relying on the fact that a

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surface charge was measured; correct?

A. That's correct. That's my understanding, yes.

Q. Okay. You weren't concerned necessarily with what those particular measurements were.

A. No. And I wasn't concerned about statistical significance relative to these kinds of trials. If we were to look at things where we were measuring a value that's found in a sample where the reliability of the test protocol that's used is going to give me a closer measure or measurements, as you see in some of the samples, you know, that would be something that I would be interested in. But I don't think that that was the purpose of either one of these trials.

Q. Now, if you saw a wide variability in results of the same testing procedure on the same sample, would that suggest to you that there might be some flaw in the method?

A. I would first repeat the test just to confirm what I'm witnessing for why there is variability. If it's a factor that I can control or correct, I would execute that factor to correct the problem. So with both of these -- even though there is variability in that test that was done by

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Burns, the point is that this still was surface charge and --

Q. No, I understand. You were still just looking --

A. Yes.

Q. -- for a surface charge measurement, but I --

A. That's all it was.

Q. I'm asking a more basic question. If you see wide variability, that could suggest a flaw in the method; right?

A. It could. It could.

Q. It could also suggest that the particular method is not very accurate?

A. It could question the accuracy. It can question even the conditions in which the study was conducted.

Q. And it could also question the reliability of the method; right?

A. Well, considering the nature of what was found in the one study -- or the one sample versus the others, there seemed to be more consistency in the other study -- or the other samples as compared to the one of the NanoBio product.

The problem there is, at least I

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investigated this a little bit further, in looking at things like the water content, the products reflect the fact that they utilized water. And in my investigation, of course this is after the fact, but looking at things like purified water versus distilled deionized water, deionized water would be removing those cations, whereas purified water may, in fact, contribute some cations. So that might be a factor. But, again, I can't confirm that because I didn't do any additional testing.

Q. Okay. Now, the conclusion that you relied on from the Burns and Ermakov testing was that both the Trutek products and the NanoBio Protect product exhibited a surface charge, and that surface charge was of the same order of magnitude; correct?

A. That's correct.

Q. And why was it important to you that the surface charge was of the same order of magnitude between the two products?

A. Just to determine the amount. That was pretty much it. Is it there or not? Does it contribute any cationic charge?

Q. Okay.

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A. Because that was part of the '802 patent's claim, is that it has this electrostatic charge and it is cationic.

Q. But if all you were interested in knowing was that the products exhibited an electrostatic charge, why did it matter to you that they were of the same order of magnitude?

A. Just to see how closely resembling they are. The cation that is used, if it's benzalkonium chloride, and the quantification therein, should be similar if the amounts are the same.

Q. And why was it important to you to know whether the surface electrostatic charge was similar between NanoBio Protect and NasalGuard?

A. Well, because the claims are being made about the product. And that's the basis of this whole proceeding, is that the two items have similarity. NanoBio and Trutek's NasalGuard products, they are similar.

Q. Okay. So when you just referred to the claims being made about the product, you're not talking about the patent claims here. You're talking about the statements made about the products on, like, the websites and non-product

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labeling; right?

A. Right. Right.

Q. I just wanted to get some terminology clear because we have "claims" used in two contexts.

A. Yeah.

Q. So how did you use the conclusion that NanoBio Protect and Trutek's NasalGuard products exhibited an electrostatic charge of the same order of magnitude in reaching your opinion on infringement?

MR. KREMEN: Objection to form.

THE WITNESS: I simply relied on the documentation that was supplied --

BY MS. PETERSON:

Q. Okay.

A. -- by both of the researchers.

Q. But how did you use that in reaching your opinion? How was it relevant to your opinion on infringement?

A. Because you have to see whether or not, in fact, if the existence of the patent -- the '802 patent preceded the marketing of the product to NanoBio, then that NanoBio product is infringing on the patented protected product of

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Trutek. I'm looking at it from that standpoint.
Q. Okay. Let me try asking the question again. So you relied on the conclusion from Burns and Ermakov that Trutek's products and BlueWillow's product exhibited an electrostatic charge of the same order of magnitude; correct?
A. That's correct.
Q. And how did you use that information to determine whether NanoBio Protect satisfies the elements of the '802 patent claims?
A. Because of where it's stated in the '802 patent. The '802 patent talks about the electrostatic charge. That's a significant factor for the methodology of how that product works.
Q. The '802 patent claims, they don't require an electrostatic charge; correct?
MR. KREMEN: Objection.
BY MS. PETERSON:
Q. That language is not in the claims; right?
A. I have to go back and take a look exactly. I'm sorry, it's late in the day.
Q. Yeah, sure. No problem. We can pull that back up. Do you have that copy of the patent handy still?

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THE REMOTE TECHNICIAN: I'm sorry, Ms. Peterson, are you speaking to me if I have that copy handy?
MS. PETERSON: No, I was asking Dr. Lemmo.
THE WITNESS: Oh, I don't have it -- no, I don't have it physically near me. That's why I'm just -- I'm rummaging around.
MS. PETERSON: Okay. Then, yeah, can we pull up on the screen Exhibit 2 and go to --
THE WITNESS: Oh, I found it. All right.
THE REMOTE TECHNICIAN: Of course I can pull it up.
MR. KREMEN: He has it.
THE WITNESS: I have it.
BY MS. PETERSON:
Q. Okay. Let's look at Claim 1.
A. Yeah.
Q. It talks about electrostatically inhibiting; right?
A. Right. Right.
Q. And electrostatically attracting; right?
A. Right.
Q. But the claims don't require a

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particular electrostatic charge.
A. Quantified?
Q. Correct.
A. No, it doesn't.
Q. Okay.
A. There's no quantification that's listed here, no.
Q. And you would also agree that the results of the Burns and Ermakov testing actually show that the electrostatic charge exhibited by the Trutek and BlueWillow products was actually different; right?
A. Quantifiably, yes.
Q. Right.
A. But, again, I go back to my statement that it wasn't a quantification. It was more of an identification that both products exhibited the electrostatic charge when applied to the substrate.
Q. Okay.
A. That's how I understood it.
Q. Okay. So if your analysis was focused on determining whether NanoBio Protect --
A. Yes.
Q. -- infringes the '802 patent claims, why

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was it relevant to you that NanoBio Protect had a surface electrostatic charge of the same order of magnitude as NasalGuard?
A. Well, it would probably -- again, it would probably reflect the composition of the NanoBio Protect relative to the amount of cation that's being contributed by the ingredients of the NanoBio Protect. So, in other words, if I look at the benzalkonium chloride content of both products, they're both going to contribute cation. And that's going to be a significant factor as far as how that product will work.
Q. Okay. So, in other words, you're assuming that because the two products had the same order of magnitude of electrostatic surface charge, they had the same ingredients?
MR. KREMEN: Objection.
THE WITNESS: I can't make that assumption because there are multiple ingredients in both products.
BY MS. PETERSON:
Q. But because they have the same order of magnitude, you're assuming that the products operate in the same manner?
A. They have similarity.

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Q. Okay. And so you considered -- so, in other words, you considered the surface electrostatic charge of NasalGuard and how it operates as part of your analysis of whether NanoBio Protect practices the elements of the '802 patent claims?
A. Yes.
Q. Okay. Let's take a look at your reply report now.
MR. KREMEN: Which one?
MS. PETERSON: It was marked as Exhibit 15.
MR. KREMEN: Okay. Exhibit 15.
THE REMOTE TECHNICIAN: Would you like me to screen share that?
MS. PETERSON: Yes, please.
THE WITNESS: Yes, please.
MR. KREMEN: His reply report, 15? Yeah, okay. Yeah, noninfringement. Okay.
MS. PETERSON: And if we could go to page 7, which is page 8 of the PDF.
BY MS. PETERSON:
Q. You see here we have a section titled "Charge Destiny Measurement Theory"?
A. Yes.

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Q. Okay. The explanation that you provided in this section, is that based on your own personal knowledge, or did you obtain this explanation from materials that you reviewed?
A. A combination of things. The materials that I reviewed, the ETS model equipment, the indicator that it was employed. So I relied primarily on that.
Q. You mean you relied primarily on the --
A. Written materials.
Q. -- explanation of the equipment used in Mr. Burns' report?
A. I relied on Mr. Burns' report and what I could find also to complement that in the literature.
Q. Okay. Now, whatever you found in the literature, you don't have it cited here; right?
A. Sometimes I do. Sometimes I don't. And I think in this particular case I did not cite anything except for the question as far as Bernardi, there was a paper that spoke about nanoemulsions. And a copy of that paper is attached. That's on the following page.
But I think much of what I wrote in reply to Dr. Amiji, because Dr. Amiji brought up

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the question of conductivity versus surface charge and whether they measured conductivity or they measured surface charge.
Q. Okay.
A. And so I needed clarification to understand what they tested and why Dr. Amiji thought that it was the measurement of conductivity as opposed to surface charge.
Q. So to just break that down a little bit, the Bernardi paper that you cite on page 8, that's related to assessing the stability of nanoemulsions; right?
A. Yes. Yes.
Q. And one of the ways that the stability was measured or assessed was by measuring the conductivity of the nanoemulsion; right?
A. Right. And, again, it depends on how the electrode -- if the electrode is actually touching the surface of the material or it's somewhere in proximity to the material. And that's the way I understand the difference between the two.
Q. Okay. But this was for the purpose of assessing the stability of the product, right, not determining whether there was a charge destiny?

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A. Yes.
Q. Okay. Yeah, I think your charge destiny discussion on page 7 might be separate from why you cited Bernardi; is that correct?
A. Yeah, it's possible that, you know, at the time I was trying to link a few factors together.
Q. Okay. So just to go back to the section where you explain charge destiny measurement theory, just to confirm, you did look at literature, but that's not cited here in your report; right?
A. Yes, that's correct. This is that which I found out in the literature.
Q. But the literature that you relied on is not identified; right?
A. Yes, that's correct. It's not identified in my report.
Q. Okay. Now, that Bernardi paper, the particular oil-in-water nanoemulsion assessed in that paper, that was a rice brand oil nanoemulsion?
A. Yes.
Q. And, again, there was no discussion in that paper of measuring electrostatic charge of

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the nanoemulsion; right?
A. No, it was mostly reflective of Dr. Amiji's reference to conductivity. And, you know, I included the Bernardi paper really in the statement that precedes where I indicate in 2011 that conductivity of the nanoemulsion is usually measured to determine the stability. The testing was not intended -- or at least what I was trying to express was that the testing that was done in the two laboratory settings was not to determine stability. It was to determine the presence of the charge.
Q. Okay. So Bernardi measured conductivity to assess stability of the nanoemulsion?
A. Yes. Yes.
Q. And you cited the Bernardi paper to support your understanding that Burns and Ermakov were testing surface charge, not conductivity?
A. That's correct.
Q. Okay. And you're aware that -- never mind. We can move on to [sic] that.
Now, another paper that you mentioned earlier -- and it's cited on the next page of your report if we move forward a page.
So on page 8, in the second full

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paragraph, this is your discussion of that -- or sorry, third full paragraph --
MS. PETERSON: If you scroll down some more.
BY MS. PETERSON:
Q. This is the paper that you mentioned regarding alternative skin models by --
A. Yes.
Q. -- Abd?
A. Abd, yes. I don't --
Q. Abd?
A. I don't know how they pronounce it, but I -- Abd, I would say.
Q. Okay. Now, you understand that this paper is directed to assessing whether it's appropriate to use alternative skin models for assessing drug permeation through the skin; right?
A. Yes. Yes.
Q. So, in other words, that's the ability of a drug or a formulation to pass through the various layers of the skin into the bloodstream?
A. Right. Right. My goal was to simply state that you can use animal models other than using human skin.
Q. Okay. This paper doesn't say anything

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about what skin -- alternative skin models might be appropriate for measuring electrostatic charge of a product applied to human skin; right?
A. No, that's correct.
Q. Okay. Let's move forward to page 10 of your reply report.
A. Sure.
Q. Okay. And here we have a situation that we have titled as "Admissions Made Directly By BlueWillow"; correct?
A. Yes, that's correct.
Q. Okay. And this would be the various statements that you identified on BlueWillow's website; correct?
A. Yes, you're correct.
Q. Okay. You didn't review any other documents showing any testing or providing any other information to substantiate that the product operates in a manner described by BlueWillow on its website; right?
A. No, I did not see that.
Q. Okay. We can go to the next page. This is page 11 of your reply report. There are four bullet points listed. And these are statements that you relied on from Nano -- from the NanoBio

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Protect website; correct?
A. Yes, from BlueWillow's website on the product NanoBio.
Q. Okay. So -- hang on a second.
That's interesting. You have four statements listed on page 10 of your -- never mind.
You've got four bullet points listed on your opening report, but they don't match up with the same four bullet points listed in your reply report, but I think we can use this.
A. Yeah, and it's possible what I was addressing at the time -- at different times that they were submitted.
Q. Okay. So looking at the third bullet point here, it says, "Dry skin allows germs to penetrate. Nanodroplets hydrate the skin, preventing dryness and cracking"; right?
A. Yes.
Q. And presumably that reference to the nanodroplets, that would be the nanodroplets of the NanoBio Protect product?
A. Yes, because I believe it comes directly from their website.
Q. Okay. So here BlueWillow is explaining

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that the nanodroplets hydrate the skin, prevents dryness and cracking, which could otherwise allow germs to penetrate the skin; correct?

A. That's correct.

Q. Okay.

MS. PETERSON: And then if we scroll -- can we scroll down a little bit to see the rest of the page.

BY MS. PETERSON:

Q. Okay. So then there's a sentence that starts, "The NanoBio Protect product adheres to the nasal tissue in a thin film. If this were not so, the liquid would immediately drip out"; correct?

A. Yes. Yes.

Q. Did you test a NanoBio Protect product to see if it forms a thin film upon application to the skin?

A. No.

Q. Did you test a NanoBio Protect product to see if any of the liquid drips out upon application?

A. No.

Q. Okay. You then go on to say that, "The nanoemulsion becomes impermeable, not allowing

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'germs to penetrate'"; right?

A. Correct.

Q. Okay. So that impermeable -- that's what we're talking about when you referenced earlier about having adequate impermeability to create a physical barrier that prevents the germs from penetrating; correct?

A. That's correct.

Q. Okay.

MS. PETERSON: Now, if you can just go up a little bit more so we can see those bullet points again.

BY MS. PETERSON:

Q. Here, wouldn't you agree that BlueWillow is saying that its product is operating to prevent germs from penetrating the skin, not by creating an impermeable thin film or a physical barrier, but rather by hydrating the skin; right?

A. Again, what we're talking about is a product that's intended not as a skin protective, but as a product that is going to help trap contaminants from entering the nasal passage. While, yes, this is going to have a benefit in hydrating the skin, but if you go back to the '802 patent with the formulations, there is also

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component parts that will add to protecting and hydrating the skin.

Q. Okay.

A. So it's not going to irritate. So there are similarities, definite similarities, intentional or otherwise, but I'm recognizing the similarities.

Q. Okay. But these statements don't reference a thin film being used to trap or hold particles; correct?

A. No, that's correct.

Q. Okay. And you would also agree that hydrating the skin to prevent germs from entering, that that's not the same as creating a physical barrier that blocks those germs from entering?

MR. KREMEN: Objection to the form of the question.

THE WITNESS: Can you repeat that or restate it?

BY MS. PETERSON:

Q. Would you also agree that hydrating the skin to prevent germs from penetrating the skin, that that's a different mechanism of action from creating a physical barrier on the skin to prevent the germs from going any farther?

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MR. KREMEN: Same objection.

THE WITNESS: Well, from going farther and setting up -- setting up a barrier so that they don't leave the treated surface to enter the nasal passage.

BY MS. PETERSON:

Q. Okay.

A. My concern was not focused on protecting dry skin as a vehicle or an entry point for microorganisms to invade. The goal, or at least the way I'm understanding it, is the role of the two products in preventing the inhalation of the harmful particles. So you see the similarities. There are --

Q. Yeah, I see the similarity in that both prevents germs from entering the system.

A. Right.

Q. But do you agree with me that they are prevented from entering the system through different physical means?

A. Yes, that's correct. One is a nanoemulsion, and the other one is not identified as an emulsion. It's a gel.

Q. Okay.

A. So physically, when you look at the

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products or at least -- I don't have that product. I don't have the physical product NanoBio. So I don't know what [inaudible].

Q. Okay. I think we're talking about two completely separate things here. The two things you were envisioning in your mind were NanoBio Protect and then Trutek's NasalGuard?

A. Right.

Q. Okay. I'm asking about something completely different.

A. Okay. All right. Let's go back over that.

Q. I'm just asking whether -- I'm asking whether hydrating the skin to prevent germs from penetrating is a different mechanism of action from creating a physical barrier on the skin?

A. Yes.

Q. Okay.

A. Yes.

MS. PETERSON: Let's go off the record.

THE VIDEOGRAPHER: We're going off the record. The time is now 5:37 p.m.

(Recess from the record.)

THE VIDEOGRAPHER: We're back on the record. The time is now 5:46 p.m.

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BY MS. PETERSON:

Q. Okay. Dr. Lemmo, I appreciate all of your time today. I know it's been a long day. I'm almost done. I just have a few other little housekeeping things to finish up on.

A. Fine. That's fine.

MS. PETERSON: Can we please mark as -- sorry, I just had a helicopter flying overhead.

MR. KREMEN: We're not going to mark that.

MS. PETERSON: Can we please mark as Exhibit 19 a copy of the Abd paper.

(Lemmo Deposition Exhibit 19 was marked for identification and attached to the transcript.)

MS. PETERSON: This is item No. 13 in my materials, Jennifer.

THE REMOTE TECHNICIAN: Yes, stand by.

BY MS. PETERSON:

Q. Okay. Dr. Lemmo, do you recognize Exhibit 19 as the paper by Eman Abd that you cited and attached to your reply expert report?

A. Yes, I do.

Q. Okay.

MS. PETERSON: We can take that down.

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And then let's mark as Exhibit 20 a copy of the Bernardi paper. This is item No. 14.

(Lemmo Deposition Exhibit 20 was marked for identification and attached to the transcript.)

THE REMOTE TECHNICIAN: Stand by.

BY MS. PETERSON:

Q. Dr. Lemmo, do you recognize Exhibit 20 as a copy of the Bernardi paper that you cited and attached to your reply expert report?

A. Yes.

Q. Great. Okay.

MS. PETERSON: Next let's mark as Exhibit 21 a copy of the Rolf patent application, which is item No. 17 in my materials.

(Lemmo Deposition Exhibit 21 was marked for identification and attached to the transcript.)

BY MS. PETERSON:

Q. Dr. Lemmo, do you recognize Exhibit 21 as a copy of United States Patent Application Publication No. U.S. 2004/0071757 issued to Rolf?

A. Yes.

Q. And this is the Rolf application that you addressed in your responsive report; correct?

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A. That's correct.

Q. Okay.

MS. PETERSON: We can take that down.

One final document. Let's mark as Exhibit 22 a copy of -- it's titled "Declaration Lemmo." This is the last document that I uploaded.

(Lemmo Deposition Exhibit 22 was marked for identification and attached to the transcript.)

MR. KREMEN: What is it specifically? Oh, okay. That's for the Matrixx case.

BY MS. PETERSON:

Q. Yeah. So, Dr. Lemmo, do you recognize Exhibit 22 as a copy of a declaration that you prepared in connection with the Matrixx litigation pending in New Jersey?

A. Yes.

MR. KREMEN: Can you go down to the signature page just to make sure that --

MS. PETERSON: Yeah, I was going to get to that, Stan.

MR. KREMEN: I want to make sure that he identifies it because it's been a long time.

MS. PETERSON: Sure.

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So can we go to the final page, please -- actually, not the final page. Go to page 7 of the PDF.
BY MS. PETERSON:
Q. Dr. Lemmo, that's your signature on --
A. That's --
Q. -- page 7; correct?
A. Yes, that's my signature.
Q. This declaration was executed on January 23rd, 2020; correct?
A. That's correct.
Q. Okay.
MS. PETERSON: Can we go back up to the top of this document.
BY MS. PETERSON:
Q. Do you see up at the top here that Amirali Haidri is identified on this document?
A. Yes.
Q. Did you have any discussions or conversations or meetings with Mr. Haidri in connection with the preparation of this declaration?
A. No.
Q. Okay.
MR. KREMEN: May I clarify something

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just for clarification? Amirali Haidri was a local counsel in this case. I was lead counsel --
MS. PETERSON: Okay. Thank you.
MR. KREMEN: -- out of state.
MS. PETERSON: Okay. Thank you, Mr. Kremen.
Can we scroll to page 3 of this declaration.
BY MS. PETERSON:
Q. Okay. And here in paragraph 8 of your declaration, Dr. Lemmo, you've provided a list of documents that you reviewed as part of your investigation; correct?
A. That's correct.
Q. And then if you go down and look at the eighth bullet point, you see the --
MR. KREMEN: What line?
MS. PETERSON: Bullet point 8. It's the eighth one down on the list. It's identified as --
MR. KREMEN: There's a line number. So if you could point out the --
MS. PETERSON: Line 13.
MR. KREMEN: Okay.

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BY MS. PETERSON:
Q. Okay. So one of the documents that you reviewed as part of your investigation was the "Determination of Surface Electrostatic Charge On Nasal Application Test Products - Test Conducted and Report Prepared by Dr. Alexei Ermakov."
Do you see that?
A. Yes.
Q. Okay. So based on this, is it your understanding that you also received a copy of and reviewed the results of Dr. Ermakov's testing of the electrostatic charge of the NasalGuard and Matrixx products?
A. Yes.
Q. Okay. And then looking at the next item in the list, it's identified as "Surface Electrostatic Charge Evaluation of Nasal Application Products - Technical Report," prepared by Shane Burns of Electro-Tech Systems; right?
A. Correct.
Q. So based on this, is it also your recollection and understanding that you received a copy of and reviewed the results of Mr. Burns' testing of the electrostatic charge of the NasalGuard and Matrixx products?

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A. Yes.
Q. Okay.
MS. PETERSON: Thank you, Dr. Lemmo. I do not have any further questions for you.
THE WITNESS: Thank you.
MR. KREMEN: Okay. Let's see, who am I talking to? Jennifer? Can you go up --
MS. PETERSON: Stan, do you have any questions for the witness?
MR. KREMEN: No, no. I'm sorry, I thought we were off the record.
MS. PETERSON: Yeah. So --
THE VIDEOGRAPHER: No, we haven't closed out the record just yet.
MR. KREMEN: I'm sorry.
MS. PETERSON: So I'm done. It sounds like Mr. Kremen doesn't have any questions. So I think we can conclude the deposition.
THE WITNESS: Okay. So I can sign off?
Have a great day. Thank you.
THE VIDEOGRAPHER: All right. Just a moment, please.
This marks the end of the deposition of Dr. Edward A. Lemmo. We're going off the record. The time is now 5:55 p.m.

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(Off the record at 5:55 p.m.)

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ACKNOWLEDGEMENT

STATE OF MARYLAND)
ss
COUNTY OF MONTGOMERY)

I, EDWARD LEMMO, PH.D., hereby certify, I have read the transcript of my testimony taken under oath in my deposition of October 24, 2022; that the transcript is a true, complete and correct record of what was asked, answered and said during this deposition, and that the answers on the record as given by me are true and correct.

_____
EDWARD LEMMO, PH.D.

Sworn and subscribed to before me this ____ day of _____, 2022.

_____
Notary Public

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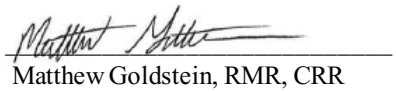
STATE OF MARYLAND)
ss:
COUNTY OF MONTGOMERY)

I, Matthew Goldstein, Notary Public within and for the State of Maryland, do hereby certify:

That I reported the proceedings in the within entitled matter, and that the within transcript is a true record of said proceedings.

I further certify that I am not related to any of the parties to the action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 24th day of October, 2022.



Matthew Goldstein, RMR, CRR

EXHIBIT 8

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff/Counter-Defendant,
v. : Case No.
BLUEWILLOW BIOLOGICS, INC., : 2:21-cv-10312
Defendant/Counter-Plaintiff,
ROBIN ROE 1 through 10
(fictitious names); ABC
CORPORATION 1 through 10
(fictitious names),
Defendants.

Videotaped Deposition of
AMIRALI Y. HAIDRI, ESQUIRE
Conducted Virtually
Friday, October 28, 2022
10:08 a.m. EDT

Job No.: 468441
Pages 1 - 96
Reported by: Debra A. Whitehead

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Videotaped Deposition of AMIRALI Y. HAIDRI, ESQUIRE, conducted virtually.

Pursuant to notice, before Debra Ann Whitehead, E-Notary Public in and for the State of Maryland.

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ALSO PRESENT:
JOHN PARKMAN, Video Specialist
JENNIFER POSIS, A/V Technician
ASHOK WAHI

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P R O C E E D I N G S

VIDEO SPECIALIST: Here begins Media Number 1 in the video-recorded deposition of Amirali Haidri in the matter of Trutek Corporation versus BlueWillow Biologics, Incorporated, et al.; in the United States District Court, Eastern District of Michigan, Southern Division; Case Number 2:21-cv-10312.

Today's date is Friday, October 28, 2022. The time on the video monitor is now 10:08 a.m. eastern time. The remote videographer today is John Parkman, representing Planet Depos. All parties of this video deposition are attending remotely.

Would counsel please voice-identify themselves and state whom they represent.

MR. KREMEN: Stanley Kremen, representing the plaintiff Trutek Corporation.

MS. PETERSON: Liane Peterson from Foley & Lardner, LLP, representing the defendant BlueWillow Biologics.

VIDEO SPECIALIST: The court reporter today is Debbie Whitehead, representing Planet Depos.

Would the reporter please swear in the

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witness.

AMIRALI Y. HAIDRI, ESQUIRE,
having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR DEFENDANT/COUNTER-PLAINTIFF

BY MS. PETERSON:

Q Good morning.

Could you please state your full name and address, for the record.

A Amirali Y. Haidri. Residential address 202 Hillside Avenue, Springfield, New Jersey, 07081.

Q Thank you. And my name is Liane Peterson. I am one of the lawyers who is representing the defendant BlueWillow Biologics in this case, and I'll be taking your deposition.

It's nice to meet you.

A Thank you. My pleasure.

Q And, Mr. Haidri, where are you physically located today?

A I am in the office of Stanley Kremen.

Q And I know that Mr. Kremen is sitting there in the office with you. Right?

A Yes.

Q Is there anybody else in the room with

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you, besides Mr. Kremen?

A No, there isn't.

Q Mr. Haidri, have you had your deposition taken before?

A Yes, I have.

Q How many times?

A Once.

Q And was your prior deposition, was that in the context of providing expert testimony or in some other capacity?

A As a plaintiff.

Q So you were the named plaintiff, and your deposition was taken in that capacity?

A That is correct.

Q Generally speaking, what was the subject matter of that case?

A I was a victim of an automobile accident. That is what the matter was all about.

Q Thank you.

Well, I will just briefly go over some ground rules, particularly since we're doing this remotely, so that we can make sure that the deposition runs smoothly. Okay?

A Yeah. Please go ahead.

Q I'm going to ask that you wait until I

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finish with my questions before you start to respond, and I'll try to do the same when you are speaking. Okay?

A Yes.

Q I'm going to also ask that you provide verbal answers to my questions, rather than shaking your head or nodding or saying uh-huh.

Is that okay?

A Yes, that is okay.

Q And if at any point you do not understand one of my questions or you need me to repeat the question, please just ask. Otherwise I will assume that you understood the question. Okay?

A Okay, I'll ask if I need clarification.

Q Mr. Haidri, are you aware of any reason why you would be unable to provide complete and truthful testimony during your deposition today?

A No.

MS. PETERSON: Let's mark as Exhibit 31 the deposition notice of Mr. Haidri, please.

(Exhibit 31 marked for identification and is attached to the transcript.)

Q Mr. Haidri, do you recognize Exhibit 31? Have you seen it before?

A I have not seen it before.

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Q But you understand that you are appearing today for your deposition pursuant to a deposition notice that was served in the Trutek versus BlueWillow Biologics matter. Correct?
A That is what I have been informed of. I have not seen this notice before.
MS. PETERSON: We can take that down.
Q Mr. Haidri, have you ever been retained to provide opinions as a testifying expert in the past four years?
A No, I have not.
Q Have you ever been retained to provide opinions as a testifying expert at any time?
A No, I have not.
Q Have you ever prepared any type of expert report or declaration for any type of contested proceeding?
A Well, not really a contested proceeding, but I'm a member of certain committees where issue joint opinions, and I have signed on on those, onto those opinions.
Q So that would be opinions that were issued for I guess certain bar-related committees that you're a member of?
A That is correct.

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Q Mr. Haidri, have you ever been retained by Trutek to provide either testifying or consulting expert services on any other matter?
A No, I have not.
Q Have you ever been retained by Trutek's -- I'm sorry, let me start that over again.
Have you ever been retained by Trutek previously in any context?
A I have been.
Q Can you explain, please.
A I was the local counsel in a certain federal court matter against a corporation called Matrixx Initiatives.
Q Apart from the federal court matter against Matrixx Initiatives, have you ever been retained by Trutek in any other context?
A I have been.
Q What other times have you been retained by Trutek?
A In a commercial litigation matter involving a breach of contract.
(Clarification by the court reporter.)
Q Are there any other instances when you've been retained by Trutek?

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A No, I have not been.
Q So just the Matrixx Initiatives matter and the commercial litigation matter involving breach of contract, those are the only two times you've been retained by Trutek?
A That is correct, as of today.
Q When was the commercial litigation matter filed?
A As best as I recall it, it was in April 2021.
Q And what court was that filed in?
A Superior Court of New Jersey, Somerset County.
Q And who was the other party?
A Their name is Jintec America, Inc.
Q And what products were involved in that case?
A It was a case of sales of the NasalGuard product that Jintec was contractually obligated to buy and pay for.
Q And what was Jintec, Incorporated's, role with respect to the sales of NasalGuard?
A Can you please repeat that? I can't understand your question.
Q What was -- the other party --

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A The defendant. Okay?
Q Okay. They were the defendant. And what was their involvement with NasalGuard?
A They entered into two different contracts for foreign markets, and they were obligated to place certain orders according to the contract. And with one particular territory they failed to place the order. And with respect to another territory, they placed an order but did not follow up with the necessary payment for the manufactured -- manufacturing of the goods involved to take place.
And -- okay.
Q And is it correct that the contracts were for purchasing NasalGuard outside of the United States?
A That is correct, for foreign markets.
Q Is that litigation still pending?
A It is pending.
Q I'd like to talk about the other matter you identified, the matter involving Matrixx Initiatives.
That matter was filed in the District Court of New Jersey. Correct?
A That is correct.

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Q And that case against Matrixx involved Trutek's claims of infringement of the '802 patent. Correct?
A It is correct, yes.
Q And that's the same '802 patent that's being asserted by Trutek in this matter against BlueWillow Biologics. Right?
A That is my understanding.
Q What was your role in representing Trutek in the New Jersey litigation against Matrixx?
A I was the local counsel for Trutek.
Q And what did you do in that role?
A I filed a complaint and served motions, pleadings, and appearances.
Q Anything else?
A Settlement -- mediation conference.
Q So you also participated in a settlement or a mediation conference with Matrixx?
Is that what you said?
A Yeah, I did participate in the mediation.
Q And was that one mediation conference that you participated in, or were there multiple?
A Only one.
Q Did you participate in any other discussions concerning settlement over the course

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of your representation of Trutek in the Matrixx matter?
A Beyond the mediation, I do not recall anything.
Q And I understand that Mr. Kremen was also counsel representing Trutek in that Matrixx litigation.
Is that correct?
A That is correct, he was my pro hac vice counsel and, in fact, lead counsel.
Q Approximately how long did the Matrixx litigation last?
A As best as I can recall, it has been close for a year or two.
Q But do you --
A A year and a half is what I would say was the length of it.
Q And do you recall when the litigation against Matrixx was filed?
A Well, if I recollect -- I can't really say that I recall for certain -- it would be about three to three-and-a-half years before now.
Q Was Mr. Kremen the lead counsel for Trutek when the complaint was first filed against Matrixx?

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A No; I was the only counsel. And then I filed a motion for Mr. Kremen to be waived in as pro hac vice counsel.
Q And Mr. Kremen was not admitted pro hac to the New Jersey Matrixx matter until about nine months after the litigation was filed. Right?
A Probably. Sounds right.
Q So for the first nine months of the litigation, you were Trutek's only attorney representing it in the matter?
A Yeah, I was the only attorney of record.
Q Do you know why you were retained by Trutek for the Matrixx litigation?
MR. KREMEN: Objection to form.
A It's because I'm an attorney admitted in the State of New Jersey, and as a registered patent attorney in the bar again.
Q Did you know Mr. Kremen before filing the litigation against Matrixx?
A I certainly did.
Q In what context?
A I was -- I was and still am a Master in the John C. Lifland American Inn of Court, and Mr. Kremen had joined a year or two before me. And that's how we met each other.

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Q And did you know Mr. Wahi or anybody at Trutek before you were retained by them to file the litigation matter against Matrixx?
A I'm not sure what you mean by whether I knew Mr. Wahi. In what context?
Can you please clarify?
Q Had you ever met Mr. Wahi before filing the case against Matrixx?
A Obviously I met with him so that he could instruct me to file the complaint.
Q Yeah, of course.
When were you first contacted by Mr. Wahi to discuss filing a complaint against Matrixx?
A Let's say, if I go by my memory, if the complaint was filed three-and-a-half years ago, then I probably met Mr. Wahi a couple of months before then to discuss what he wanted me to do.
Q So prior to the time that Mr. Wahi contacted you to discuss the potential litigation against Matrixx, you had never met him before?
A No, I had not.
Q So just to confirm, it was Mr. Wahi who contacted you about filing the case against Matrixx, and not Mr. Kremen?
A Actually, it's not as simple as that.

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Mr. Kremen introduced me to Mr. Wahi.
Q And then after Mr. Kremen introduced you to Mr. Wahi, you had some meetings or discussions with Mr. Wahi to discuss the potential litigation matter against Matrixx.
Is that right?
A That is correct.
Q Okay. So would it be fair to say then that during the course of your representation of Trutek in the Matrixx matter, you did communicate directly with Mr. Wahi of Trutek?
A And his office, Trutek Corporation, yes.
Q Who else did you communicate with at Trutek in connection with the Matrixx litigation matter?
A The president of Trutek and another vice-president.
Q Do you recall their names?
A I do.
Q What are their names?
A The president is called Shaheda Ashtekar.
Q And then who was the other vice-president that you communicated with in connection with the Matrixx litigation matter?
A Kanika Wahi.

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Q What was the first name?
A Kanika.
Q Kanika?
A Do you want me to spell it?
Q Sure.
A K for Kenneth, A for apple, N for Nancy, I for Irene, K for Kenneth, A for apple.
Q Is that Mr. Wahi's daughter?
A That's what I'm told.
Q Could you spell the name of the President of Trutek that you identified earlier?
A Indeed I will. S for Sam, H for Harry, A for apple, H for Harry, I for Irene, D for dog, A for apple. Shaheda.
Q And that's his first name or last name?
A It's her first name.
Q Her first name. Okay. What is her last name?
A Ashtekar.
Q Ashtekar?
A Ashtekar, yes.
Q Okay. Thank you.
Now, with respect to Ms. Wahi, do you know what she was vice-president of? Did she have a -- was she responsible for certain things in

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that role?
A I'm sure she was. I'm not aware of what exactly her responsibilities.
Q Do you know, like, was she a vice-president in charge of some particular operation of Trutek?
A I'd rather not guess. But she was vice-president, that's all I can say.
Q Okay.
A Still is, as a matter of fact.
Q Now, during the course of your representation of Trutek in the Matrixx matter, did you also communicate directly with opposing counsel representing Matrixx?
A I did.
Q And you understand that Matrixx also filed a petition for inter partes review at the Patent and Trademark Office with respect to the '802 patent. Right?
A That is what I'm told. I don't know anything more about it.
Q Did you have any role or did you participate at all in that IPR proceeding involving the '802 patent?
A No, I was not involved.

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Q At the time of the Matrixx litigation, did you review or -- did you review the petition for the IPR?
A I believe I saw it. I can't recall exactly anything about it.
Q Were you asked by anyone to review the petition and provide your analysis of the petition?
A No, I was not.
Q During the nine-month period after the Matrixx litigation was filed, before Mr. Kremen entered an appearance, what was your responsibility for handling the litigation matter for Trutek?
A Well, I was the counsel. That's all I can say.
Q So would it be fair to say that you were responsible for running that litigation and overseeing all aspects of the litigation during that time period?
A Doing what I needed to do with the court and opposing counsel.
Q And you understand that Matrixx raised several allegations of invalidity of the '802 patent in that litigation pending in New Jersey.

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Correct?
A Well, they have the usual defenses any infringer raises.
Q And so you were responsible for assessing those defenses and considering responses to them.
Right?
A I have to, yes.
Q Approximately how much time do you think you devoted to handling the Trutek litigation matter pending in New Jersey over that year-and-a-half period?
A I can't give you an exact estimate. It would be hundreds of hours, I'm sure.
Q And over the course of representing Trutek in the Matrixx litigation, did you review the '802 patent?
A Yes, I reviewed it a few times.
Q And did you consider the disclosure of the '802 patent?
A I have seen it, yes.
Q And I'm asking specifically, did you consider or review the disclosure of the '802 patent in the context of your work in representing Trutek in the Matrixx litigation matter?
A Broadly speaking, yes.

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Q And did you assess the claim scope of the '802 patent over the course of your representation of Trutek in the Matrixx litigation matter?
A Will you please repeat that question?
Q Did you assess the claim scope of the '802 patent over the course of representing Trutek in the Matrixx litigation matter?
A Yes, I did.
Q Did you assess Trutek's claims of infringement of the '802 patent over the course of representing Trutek in the Matrixx litigation matter?
A Yes.
Q Did you assess claim construction of the '802 patent in the course of representing Trutek in the Matrixx litigation matter?
A Informally, yes.
Q And when you say "informally," that's because the court never conducted formal Markman proceedings in the Matrixx matter.
Is that correct?
A There was no Markman hearing.
Q And did you assess the validity of the '802 patent in the course of representing Trutek in the Matrixx litigation matter?

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A I certainly considered it to be valid, if that is your question.
Q Did you assess the validity of the '802 patent in response to invalidity defenses raised by Matrixx --
MR. KREMEN: Objection. Form.
Q -- while representing Trutek?
MR. KREMEN: I'm sorry. Objection to form.
A And I didn't quite understand. That was a long question.
Q Well, I'll try to rephrase the question and get it all out at once.
A Okay.
Q While representing Trutek in the Matrixx litigation matter, did you assess the validity of the '802 patent in response to the invalidity defenses raised by Matrixx?
A Yes, I did.
Q So would it be fair to say that over the course of representing Trutek in the Matrixx litigation, you obtained an understanding of the '802 patent and the prior art?
A Yes.
Q And your experience in representing

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Trutek in the Matrixx litigation informed your understanding of the '802 patent and the prior art. Right?
A That is correct.
Q Did you draw on what you learned while representing Trutek in the Matrixx litigation when forming your expert opinions that you prepared for the present litigation?
A Yeah, somewhat.
Q In what context, or how did they inform your opinions?
A Well, I was aware of the art cited against the '802 patent, the one and only office action there was, and what the patent as granted truly stands for.
Q And when you say what the patent as granted stands for, you're talking about the disclosure of the patent and the invention claimed in the patent. Correct?
A Yes, that is true.
Q And your understanding of the disclosure of the '802 patent and the invention claimed in the '802 patent, did that come from discussions with Mr. Wahi or anybody at Trutek?
A Not really. I just studied the papers

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connected with the patent and what led to it.
Q Did you ever discuss with Mr. Wahi over the course of representing Trutek in the Matrixx litigation his view of the '802 patent and what it discloses and what it claims?
A No, I did not.
Q Did you discuss with Mr. Kremen while representing Trutek in the Matrixx litigation the disclosure of the '802 patent --
A Yes.
Q -- and what it claims?
A Yes.
Q Did you discuss with Mr. Kremen while representing Trutek in the Matrixx litigation any issues addressed to the invalidity challenges to the '802 patent?
A I don't recall. I don't think I did.
Q In your meetings with Mr. Wahi leading up to the filing of the Matrixx litigation, did Mr. Wahi provide you any information about his view of the '802 patent?
A No, I don't think so.
Q Have you ever been retained by Mr. Kremen previously on any other matter?
A Well, we jointly represented a certain

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plaintiff in a patent case.
Q That's a different patent case not involving Trutek?
A Nothing to do with Trutek.
Q And that was a litigation matter?
A Two of them. They were both litigation matters.
Q And who was the party that you jointly represented with Mr. Kremen?
A You mean the name of the plaintiff?
Q Yes.
A William Araujo.
Q Can you spell that last name?
A A-R-A-U-J-O.
Q Was that a patent infringement matter?
A Yes, there were.
Q When were those filed?
A One was filed in the District of New Jersey.
Q Okay. Where was the other filed?
A Southern District of New York.
Q And when were those two litigations filed?
A Time frame?
Q Yes.

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A The first one would have been over about a couple of years ago. Second one just came to an end within this month.
Q And those two litigation matters, you said the name of the plaintiff that you represented was William Araujo. Right?
A Araujo, right.
Q Was he the inventor on the patent?
A He was.
Q Other than those two litigation matters representing Mr. Araujo, have you ever jointly represented a party in litigation with Mr. Kremen?
A Well, there was a trademark infringement matter where he was a consultant with me, but not an attorney of record.
Q Okay. Anything else?
A No, nothing else.
Q And what about Mr. Keith Altman; have you ever worked with Mr. Altman on any litigation matters before this one?
A Never met him.
Q And apart from the Trutek matter filed against Matrixx, the present Trutek matter filed against BlueWillow Biologics, and the breach-of-contract action that you identified,

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have you ever been retained by Trutek on any other matter?
A No, I don't think so. In fact, I have not been.
Q I'd like to focus now on your retention for this particular matter involving BlueWillow Biologics. Okay?
A Okay, I'm listening.
Q When were you retained as an expert in this matter?
A It will be about three or four months ago.
Q And who were you retained by?
A By Mr. Kremen.
Q And what did Mr. Kremen explain to you about what you were going to be requested to do?
A Well, he explained that I had to provide a report defending the validity of the '802 patent.
Q Did Mr. Kremen provide you with any materials that he asked you to consider in forming your opinions regarding the validity of the '802 patent?
A Yeah, I received some materials.
Q What did you receive?

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A A report from Dr. Amiji and prosecution history of the '802 patent, other prior publications that may have some relevance.
Q Can you identify those prior publications for me?
A As best as I recall, there are two patents of some -- that have been mentioned a few times, called Wadstrom and Rolf. And they are not, in fact, patents, but they are publications.
Q And do you recall any other materials that Mr. Kremen provided you with in connection with forming your opinions regarding the validity of the '802 patent?
A Many other materials. Names I recall are Baker and Khaled.
Q So basically that's the prior art that's addressed in your report. Right?
A If you want to call it prior art, that's what it is.
Q Did Mr. Kremen provide you any other materials or documents or information that you used to form your opinions that are not specifically identified in your report?
A No, I can't say he did.
Q Mr. Haidri, do you intend to testify at

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the trial if it occurs in this matter?
A Well, it will be up to the parties and Mr. -- if I'm asked, I will testify, yes. I haven't been asked.
Q And will you be -- if you are asked to testify at the trial if one occurs, will you be compensated for your testimony?
A I would expect that that's the usual thing in litigation.
Q And what rate will you be compensated at for your testimony at trial?
A Well, it depends on when the trial takes place. But my billing rate at present is $350 an hour.
Q And that's the rate that you have billed Trutek for the work that you have conducted in this matter filed against BlueWillow?
A That is right.
Q How many hours have you spent on this matter involving BlueWillow in preparing your opinions?
A I don't have my billing sheet before me, but my best estimate is it's 40 to 50 hours.
Q Did you speak with anybody other than Mr. Kremen in connection with your work on this

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matter involving BlueWillow Biologics?
A No, I have not.
Q So you have not had any conversations with Mr. Wahi since you have been retained as an expert in this matter?
A Well, that's not so simple to answer. But, no, in this context, I have not spoken to Mr. Wahi. I have the other litigation pending, therefore I will speak to him regularly.
Q That would be the breach-of-contract litigation?
A That is correct.
Q Did you speak with anybody else at Trutek since -- strike that.
Did you speak with anybody else at Trutek in connection with forming your opinions on the BlueWillow Biologics matter after being retained?
A No.
Q Did Mr. Wahi or anybody else at Trutek provide you with any information that you used to form your opinions in this matter?
A No.
Q Did you rely on any information provided by Mr. Wahi during the earlier litigation when forming your opinions on the BlueWillow Biologics

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matter?
A I'm not sure I understand your question, but I think -- I think the answer is no.
Q I can rephrase that.
Did you receive any information or any documents from Mr. Wahi at any time that you used or considered when forming your opinions in the BlueWillow Biologics matter?
A Then I stand with my answer. The answer is no.
Q Did you receive any information or any documents from anybody at Trutek at any time that you used or considered when forming your opinions in the BlueWillow Biologics matter?
A No.
Q Now, over the entire course of your representation of Trutek, how many times do you think you've spoken to Mr. Wahi?
A Dozens of times, in various different context, not just the -- not just the Matrixx matter or the breach-of-contract matter.
Q How many times do you think you spoke to Mr. Wahi in connection with one of the matters involving the '802 patent?
A How many times I cannot possibly recall.

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Must be dozens of times.
Q And did any of those conversations relate to prior art asserted against the '802 patent?
A I don't think so. I cannot recall that.
Q I'm sorry. Is your answer that you don't remember or that you don't believe so?
A I don't believe so.
Q Did any of your dozens of conversations with Mr. Wahi relate to the disclosure of the '802 patent?
MR. KREMEN: Objection to the form of the question.
A The answer is no.
Q So Mr. Wahi never explained to you what he invented in the '802 patent?
A No, he didn't. I just know what the patent says.
Q Did any of your conversations with Mr. Wahi relate to his claims that other companies have been infringing the '802 patent?
A Obviously he informed me that Matrixx Initiatives was infringing. Or that that was his opinion.
Q Did he explain to you his explanation for why he believes that Matrixx was infringing?

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A Yeah, he explained.
Q And in the context of providing that explanation, did he provide any explanation about the scope of the '802 patent or the claimed invention of the '802 patent?
A Indirectly. He just pointed out what the Matrixx product called Zicam involved, and how it read upon the claims of the '802 patent.
Q And you understand that Trutek has retained the services of other experts in this present litigation. Correct?
A I'm aware of a few names, yes.
Q Have you spoken with any of the other experts retained by Trutek in this litigation?
A I know one of them, but I haven't spoken to him in the context of this litigation.
Q And who is that?
A Dr. Lemmo.
Q And how do you know Dr. Lemmo?
A He was an expert in the Matrixx litigation.
Q What was he asked to opine on in the Matrixx litigation?
A Broadly on the subject of infringement.
Q Anything else?

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A I don't recall now.
Q Did you speak to Mr. -- or, I'm sorry, did you speak to Dr. Lemmo in connection with the Matrixx litigation?
A No, I have not.
Q So have you ever had any conversation with Dr. Lemmo at any point in time?
A Well, not since the conclusion of the Matrixx litigation I haven't spoken to him.
Q Did you have any conversations with Dr. Lemmo during the course of the Matrixx litigation?
A Yeah, I met him one time and may have spoken to him by telephone a few times.
Q And what was the purpose for that one meeting with Dr. Lemmo?
A He was retained as an expert for Trutek in that litigation.
Q So why did you meet with him? What did you discuss at that meeting?
A The scope of the patent claims, and more importantly what the composition of the Zicam product was and if it read upon the claims and we had a basis for proving infringement.
Q Did you have any conversations with

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Dr. Lemmo during the course of the Matrixx litigation concerning any invalidity challenges raised against the '802 patent?
A No, I was not involved.
Q Who was involved in those?
A Mr. Kremen.
Q And just to confirm, you have not met with or spoken to Dr. Lemmo since the Matrixx litigation concluded?
A I have already said that.
Yes, I have not.
Q Have you reviewed any of the reports that Dr. Lemmo prepared in this litigation filed against BlueWillow Biologics?
A Yes, I have.
Q Which of Dr. Lemmo's reports or declarations have you reviewed?
A They're not before me, so I cannot tell you exactly what, but he did render an opinion that I have read.
Q And do you recall when you read that opinion rendered by Dr. Lemmo?
A It will be sometime this month.
Q So --
A October, that is. October 2022.

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Q So you reviewed at least one of Dr. Lemmo's reports sometime this month.
A That is correct.
Q Did you review any of Dr. Lemmo's reports or declarations before you formed the opinions that you provided in your expert report?
A Actually, I don't think so. Chronologically I probably saw his report after mine was prepared.
Q And then what about the other two experts retained by Trutek in this matter, Mr. Burns and Dr. Ermakov. Do you know those names?
A I've heard those names. I haven't met them.
Q You have never met Mr. Burns in any context.
Is that correct?
A That is correct.
Q And have you ever met Dr. Ermakov in any context?
A No.
Q Did you meet with Mr. Burns or have any conversations with Mr. Burns in connection with the Matrixx matter?
A No.

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Q Did you meet with Dr. Ermakov or have any conversations with Dr. Ermakov in connection with the Matrixx matter?
A No.
Q And you understand that Mr. Burns and Dr. Ermakov conducted testing in connection with the Matrixx matter. Correct?
A I cannot say that I know that for sure. I've just been told that.
Q Well, the testing that Dr. Ermakov and Mr. Burns conducted on the Matrixx products, that was part of the record in the Matrixx litigation, was it not?
A I do not recall that.
Q Were you involved in the decision to engage Mr. Burns or Dr. Ermakov to conduct any testing for Trutek in either litigation matter?
A No.
Q Have you reviewed any of the reports prepared by Mr. Burns or Dr. Ermakov in either of the litigation matters?
A No.
Q Now, specifically with respect to this litigation, did anybody else assist you in formulating the opinions that are contained in your expert report?
A No.
Q Now, you've submitted one expert report in this matter. Correct?
A Yes.
Q What was the nature of your assignment?
A To rebut the allegations of invalidity put forth by your expert, Dr. Amiji.
Q Does your responsive report contain all of the opinions that you have formed directed to the issue of validity of the '802 patent?
MR. KREMEN: Objection to the form of the question.
A Well, I don't want to put myself in some kind of a conundrum, but yes. Basically, generally speaking, the answer is yes. But I reserve the right to issue any amendments.
Q But as of today you do not have any amendments or any changes to your report?
A No.
Q Does your responsive report contain a complete statement of all of the bases for your opinions?
A Complete statement as of the time it was prepared. But as I said earlier, supplements and

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amendments are still a possibility.
Q Yeah, of course. I'm just referring to the report as it was prepared.
So the answer is, yes, the report as prepared contains a complete statement of all of the bases for your opinions?
A Yes, on the date it was prepared. Yes.
Q And does your responsive report contain a complete statement of your qualifications directed to the subject matter of your opinions?
A My qualifications are what they are, yeah.
Q Did you draft the expert report by yourself?
A Yes, I did.
Q Did you receive any assistance in drafting your report?
A No; only background materials that were supplied to me, including in particular Dr. Amiji's report and whatever Dr. Amiji refers to.
Q What other background materials were supplied to you?
A Well, as I said to you before -- it's already on the record -- the Wadstrom and the Rolf

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patents, Khaled, Baker, and a few others.
Q So you're talking about the references discussed by Dr. Amiji. Correct?
A Prior publications, yes.
Q What I'm asking about is whether there are -- strike that.
So every section of your responsive report is your own opinion and drafted in your own words.
Is that correct?
A That is correct.
Q Mr. Haidri, what did you do to prepare for your deposition today?
A I reviewed -- rereviewed my own report and deposition of Dr. Lemmo and the reports of Dr. Amiji.
Q Did you review the deposition transcript of Dr. Amiji?
A Yes.
Q Did you review any other materials to prepare for your deposition today, besides your report, Dr. Lemmo's transcript, Dr. Amiji's report on invalidity, and Dr. Amiji's deposition transcript?
A That is correct. I can't say that that's

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everything, but I did look at the prior art citations and the first office action that issued in the '802 patent.
Q So you reviewed each of those items, in addition to some prior art, as well as the first office action issued in the '802 patent.
Is that correct?
A Broadly speaking, yes.
Q Do you recall any -- never mind.
Did you meet with anybody to prepare for your deposition today?
A I met with Mr. Kremen.
Q For how long?
A A few hours.
Q And when did that meeting occur?
A Over a couple of weeks on and off.
Q So you spoke with Mr. Kremen on a few occasions over the last few weeks for a few hours in total.
Does that sound about right?
A That is right.
Q Did you meet with or speak to anybody else to prepare for your deposition today?
A Nobody else.
Q Did you meet with or speak to anybody at

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Trutek to prepare for your deposition today?
A No.
MS. PETERSON: How about we go off the record.
VIDEO SPECIALIST: We're going off the record. The time is now 11:09 a.m.
(A recess was taken.)
VIDEO SPECIALIST: We're back on the record. The time is now 11:20 a.m.
BY MS. PETERSON:
Q Mr. Haidri, one other question about the Matrixx litigation.
Why did Mr. Kremen not apply for pro hac vice admission for the Matrixx litigation matter until nine months after the complaint was filed?
MR. KREMEN: Objection to form.
A It's because Mr. Kremen was not a member of any bar at the time the complaint was filed.
Q So for the nine months leading up to that point in time, you were the only attorney representing Trutek that was a member of any state bar of the United States?
A I was, yes, only attorney.
Q Mr. Haidri, we're going to show you a couple of exhibits during the rest -- the

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remainder of the deposition. Jennifer is going to put those up on the screen. And if you would like us to move through them just ask us, and we can zoom in or we can scroll through. Okay?
A All right.
MS. PETERSON: So let's mark as Exhibit 32 a copy of Mr. Haidri's CV.
A/V TECHNICIAN: Stand by, please.
(Deposition Exhibit 32 marked for identification and is attached to the transcript.)
Q Mr. Haidri, do you recognize Exhibit 32 as a copy of your CV?
A It is. It is, yes.
Q Is it complete?
A Complete as of today, yes. About to make some revisions.
Q You have some revisions to include. Would that be more recent information, to include in the CV?
A More recent, yes.
Q Do you have any other revisions to make apart from the more recent things to include?
A No, there are no revisions to make as of today, but there will be some coming.
Q Now, it looks like you obtained your

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bachelor's degree in 1971. Correct?
A Yes.
Q And at that point in time -- actually, we could scroll down to the second page.
A Okay.
Q Actually, I take that back. Let's go to the very last page.
There we go. And we can start at the bottom.
So after obtaining your bachelor's degree in 1971, you started to work for W.P. Thompson & Company. Correct?
A Correct.
Q And that involved trademark work?
A Yes.
Q And from there you went to Haseltine & Lake from 1972 to 1981. Correct?
A Correct.
Q And that also involved trademark work?
A Yes.
Q And then it looks like in 1980, over that time frame, that's when you obtained your J.D.?
A In '80, yes.
Q And then in 1981, from 1982, you worked for the Texaco Development Corporation?

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A Yes.
Q And your responsibilities at Texaco were as a patent attorney. Correct?
A Correct.
Q We can scroll up.
And then from 1982 to 1984 you were employed by Lever Brothers Company, also has a patent attorney. Correct?
A Yes.
Q And scroll up, please. There we go. That's good.
And then it looks like from 1984 to 1988 you were a partner in the law firm of Haidri, Glazer & Kamel.
Is that correct?
A Yes.
Q And your practice at that law firm concentrated in personal injury and workers' compensation claims.
Is that correct?
A Substantially, yes.
Q And then starting in 1988 to the present, it says that you have been a solo practitioner.
Right?
A Yes.

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Q And what would be -- what would you say is the primary focus of your work over that time frame as a solo practitioner?
A It had been tort and insurance law up to about two, three years ago. But I began to return to patent and trademark and commercial litigation practice.
Q So from 1988 up until about two to three years ago, your practice had been tort and insurance law?
Is that right?
A Yes.
Q And then about two to three years ago you returned to patent, trademark, and commercial litigation practice.
Is that correct?
A I began to diversify then, and that would be correct.
Q So over the last two to three years, are you still engaged in tort and insurance law claims?
A Yes. Yes, I am.
Q Over the last two to three years, what would you say has been the approximate percentage of your work relating to patents?

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A Possibly 20 percent.
Q And would most of that work relating to patents involve the matters on which you have been engaged by Trutek?
A And Mr. Araujo.
Q Mr. Haidri, you do not have any experience in the formulation or development of oil and water nanoemulsions. Correct?
A No; I have to disagree.
Q What experience do you have in the formulation or development of oil and water nanoemulsions?
A In Texaco Development Corporation, they had work of that kind going on in patents directed to it. And also in Lever Brothers Company, which is a rather diversified company; not just concentrating in soaps and detergents and toothpaste.
Q So would it be fair to say that your experience with nanoemulsions at Texaco and with Lever Brothers was from the context of being a patent lawyer?
A Yes; not as an inventor, but I was a patent attorney. Yes.
Q So you were not in the laboratory at

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Texaco or at Lever Brothers actually making any nanoemulsions or testing any nanoemulsions.
Correct?
A Well, I would say yes, I had frequent contact with the inventors and went into the laboratories in both corporations.
Q But you, personally, were not involved in the production or formulation of any nanoemulsions while employed by Texaco or Lever Brothers.
Right?
MR. KREMEN: Objection to form.
A I did not personally do it, do that.
Q And the work that was being conducted at Texaco and Lever Brothers with respect to nanoemulsions, those were not nanoemulsions intended for nasal administration. Correct?
A I would not agree, no.
Q Okay. Can you explain?
A Not at Texaco but At Lever, they were engaged in personal products, and some of them would be for just any kind of human application.
Q And that would be the soaps?
A Not really. They had -- during my time there, they had different certain uses for something called Sanosil analytes, and they

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believed that that would be beneficial in human used in just about any bodily cavity.
Q Would it be fair to say that you do not have any hands-on experience in preparing any nanoemulsion -- any nanoemulsions?
A Not during my employment, but certainly during the laboratories of my alma maters and my high school.
Q So you're telling me that you prepared nanoemulsions in high school?
A Emulsions of various kinds, not necessarily nano. But we were taught how emulsions are made, and we made them.
Q In what high school course were you taught about emulsions and how to make them?
A Physics and chemistry and biology.
Q So you're talking about high school level of physics, chemistry, and biology courses?
A Yes.
Q Dr. Haidri, do you have any hands-on experience in formulating pharmaceutical compositions that are intended to be applied to the nose?
A No hands-on experience, but I had involvement as a patent attorney, or inventors who

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were doing that.
Q And was that experience something that you obtained from representing Trutek?
A No. That was at Lever Brothers.
Q Lever products. Okay.
Do you have any hands-on experience in formulating pharmaceutical compositions that are intended to inhibit infection caused by bacteria?
A No hands-on experience, but only as a patent attorney.
Q And that would be from reviewing materials provided by the inventors for purposes of applying for a patent?
A That is correct.
Q Do you have any hands-on experience in formulating pharmaceutical compositions that are intended to inhibit infection caused by viruses?
A As a patent attorney, you have to understand that an inventor provides you just a very sketchy idea of it, of an invention. And the patent attorney has to put meat on the skeleton. So I have been involved in that.
Q Now, apart from your work as a patent attorney, do you have any hands-on experience in formulating pharmaceutical compositions that are

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intended to inhibit infection caused by viruses?
A No.
Q Apart from your work as a patent attorney, do you have any hands-on experience in formulating pharmaceutical compositions that are intended to inhibit the nasal inhalation of any environmental particulate matters?
A No.
Q Apart from your work as a patent attorney, do you have any hands-on experience in formulating pharmaceutical compositions that are intended to capture and hold particulate matter within the human nose?
A No.
Q Apart from your work as a patent attorney, do you have any hands-on experience in formulating pharmaceutical compositions that comprise cationic or anionic agents?
A No.
Q Apart from your work as a patent attorney, do you have any hands-on experience in formulating pharmaceutical compositions that comprise biocidic agents?
I'm sorry, are you still thinking about my question, or do you need me to repeat it?

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A I didn't hear your question.
Q Okay. So apart from your work as a patent attorney, do you have any hands-on experience in formulating pharmaceutical compositions that comprise biocidic agents?
A No.
Q Apart from your work as a patent attorney, do you have any hands-on experience in formulating pharmaceutical compositions with biocidic agents for application for nasal administration?
A No.
Q Apart from your work as a patent attorney, do you have any hands-on experience in formulating pharmaceutical compositions comprising biocidic agents to use them to inhibit infection by bacteria or viruses?
A Please repeat that question. That was rather long.
Q Okay. No problem.
Apart from your work as a patent attorney, do you have any hands-on experience in formulating pharmaceutical compositions that use biocidic agents for the purpose of inhibiting infection by bacteria or viruses?

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A No.
Q Do you have any hands-on experience in testing any pharmaceutical compositions to confirm whether they will work for their intended purpose?
MR. KREMEN: Objection to the form of the question.
A No.
Q Do you have any hands-on experience in testing pharmaceutical compositions to determine if they are affective to capture and hold particulate matter within the nose or nasal passage?
A No.
Q Do you have any hands-on experience in testing pharmaceutical compositions to determine if they are effective to inhibit infection by bacteria and viruses?
A No.
Q Do you have any hands-on experience in developing or formulating pharmaceutical products intended to prevent infection caused by the common cold?
MR. KREMEN: Would you repeat that again? I lost -- I got lost in the middle of it.
MS. PETERSON: Sure, I can repeat it.

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Q Mr. Haidri, do you have any hands-on experience in developing or formulating pharmaceutical products intended to prevent infection caused by the common cold?
A No.
Q Do you have any hands-on experience in developing or formulating pharmaceutical products intended to prevent infection caused by the flu?
A Hard for me to say. But broadly speaking, I will say no.
Q Mr. Haidri, you do not have an economics or accounting degree. Correct?
A Technically, yes; except that I had economics courses in my education.
Q Mr. Haidri, would it be fair to say that over the course of your career working for private companies, you were not primarily engaged in the sales or marketing or advertising of any commercial products?
A No.
Q I'm sorry, I need to clarify. No, you were not engaged in the sales or marketing or advertising of any commercial products?
Is that correct?
A Yes, that is correct.

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Q And would it also be fair to say that over the course of your career working for private companies, you did not have any job responsibilities for product development?
A No.
Q So no, you did not have any responsibility for product development of any commercial products at your prior employers?
A No; only as a support patent attorney.
Q And at your prior employment, did you have any responsibility for any clinical testing or clinical development of commercial products?
A Not with prior employments, employers, no.
Q But you did as a patent attorney?
A No.
Q Do you have any experience in human clinical testing?
A No, not personally.
MS. PETERSON: Okay. We could take down that exhibit.
Next I would like to pull up a copy of Exhibit 2, which had been previously marked. This is a copy of the '802 patent.
(Exhibit 2, previously marked, not

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attached.)
Q Mr. Haidri, we've put up on the screen here a copy of U.S. Patent Number 8,163,802, which has been marked as Exhibit 2.
Do you recognize this?
A Yes, I do.
Q And you recognize this as a copy of the '802 patent that's being asserted in this litigation against BlueWillow. Correct?
A That is what I have been informed.
Q This is the patent that you considered in your expert report. Right?
A Yes.
Q Let's scroll down to the last page.
MR. KREMEN: Excuse me. Debbie or whoever, could we zoom in one level so that it fills the screen? Because Mr. Haidri has difficulty seeing it. Thank you so much.
THE WITNESS: Thank you.
MS. PETERSON: Could we go to the last page of the exhibit, please. Actually, I'm sorry, second-to-last page. Yep. And maybe scroll down a little bit. And then -- okay.
Q Mr. Haidri, do you see Claims 1 and 2 listed on the screen in front of you?

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A Yes.
Q So I'd like to focus on Claim 1. You'd agree with me that Claim 1 has a preamble?
A A method -- yeah, okay, I see the preamble.
Q And then following the preamble of Claim 1, there are three claim elements. Right? A, B, and C?
A Yes.
Q Element -- and looking at the preamble, it refers to a method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.
Correct?
A That's what it says.
Q And then going on, Wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film.
Correct?
A Yes.
Q And it's your understanding that this language of the preamble is limiting. Right?
A Limiting in what sense? I didn't follow you.
Q Is it a claim limitation?

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A It's not a limitation. That's what the claim says.
Q For a product to read on the claim, is it necessary to satisfy the elements of the claim preamble?
A The claim as a whole. You cannot split it into different parts and say, for this reason this doesn't read. You have to consider the claim as a whole.
Q But you agree with me that every element of the claim must be present in an accused product for it to read on the claim. Correct?
A Generally speaking, yes.
Q And that would include the elements of the claim preamble. Right?
A It would.
Q So looking at Element A, it recites, "Electrostatically attracting the particulate matter to the thin film."
Right?
A That's what it says.
Q And that's what you referred to in your report as capturing?
A It's a equivalent term, yes.
Q Well, you did use the phrase "capturing"

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in your report with respect to Element A of the claims. Right?
A Yes.
Q And then Element B recites, "Holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film."
That's the element that you referred to in your report as holding. Right?
A Yes, it is holding in general.
Q And then the final element of Claim 1 is, "Inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless."
That would be the element you referred to in your report as killing. Correct?
A Killing or biocide, yes.
MS. PETERSON: Can we scroll down a little bit to look at Claim 2.
Q Claim 2 is another independent claim, except that it recites a formulation instead of a method. Correct?
A Yes.

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Q But it requires those same three elements of catching, holding, and killing as you described in your report?
A That is correct.
Q Now, do you agree that Claims 1 and 2 do not recite just a formulation having certain ingredients?
A Would I agree with what? I'm not sure what you mean.
Q Well, Claims 1 and 2 are not drafted as a formulation containing a list of ingredients.
Correct?
A No, no formulations are included.
Q Rather, the claims are drafted with respect to the catching, holding, and killing functions that you identified. Right?
A Only the functions, yes.
MS. PETERSON: Could we zoom that out and move forward a few pages to --
MR. KREMEN: Go one more page.
MS. PETERSON: -- Page 4 of the PDF?
A/V TECHNICIAN: I'm sorry, Counsel, which page?
MS. PETERSON: Page 4 of the PDF.
Q And, Mr. Haidri, you understand that the

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'802 patent contains ten tables with a list of formulations. Correct?
A Yes.
Q And the formulations provided in those ten tables contain a number of ingredients listed.
Right?
A That is correct.
Q And for many of those ingredients, rather than providing a specific amount of the ingredient, it's provided in terms of a range.
Right?
A It is correct.
Q And you understand that there is nothing in the '802 patent indicating that any of these formulations were made. Correctly -- correct?
MR. KREMEN: Object to the form of the question.
Q Let me ask that question again. That was bad.
You understand that there is nothing in the '802 patent specifically stating that any of these formulations were made. Correct?
MR. KREMEN: Objection.
A There is no indication as to whether the, formulations were made or not made. That is not

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clear from the specification.
Q And there's nothing in the '802 patent specification indicating that any of these formulations were tested to whether they performed the functions recited in the '802 patent claims.
Right?
A Again, I repeat my previous answer. You cannot say yes or no. But this is not included in the specification.
Q So the specification does not include anything about any testing of the formulations to determine whether they perform the functions recited in the '802 patent claims. Right?
A There is no such recitation in the specification.
Q And there is no -- nothing in the '802 patent that reports the surface charge of any of the formulations listed in Tables 1 through 10?
A Can you repeat that? I don't understand what you mean by "surface charge."
Q Is there anything in the '802 patent that reports the testing of any of the formulations listed in the tables to determine whether they exhibit an electrostatic charge?
A It is not mentioned explicitly, but there

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are compounds here which are known to be cationic.
Q Is there anything in the '802 patent that reports the testing of any of the formulations listed in the table to determine whether they exhibit an electrostatic charge when applied to the skin in or around the nose of a human?
MR. KREMEN: Objection to the form of the question.
A I would ask that that question be repeated. It's a little too long and convoluted.
Q It might help too, if I can get the entire question stated on the record before anyone else speaks. But I can certainly repeat it.
Is there anything in the '802 patent that reports the testing of any of the formulations listed in the tables to determine whether they exhibited an electrostatic charge when applied to a human nose?
A There is no such expletive mentioned, yes.
Q Does the '802 patent identify any specific test that someone could use to determine whether a formulation electrostatically inhibits harmful particulate matter from infecting an individual through nasal inhalation?

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A That is a -- that is a general teaching of the specification, and that's what it's intended for.

Q But does the '802 patent identify any type of test or procedure that someone could use to determine whether their product electrostatically inhibits harmful particulate matter from infecting an individual through nasal inhalation?

A Again, the teaching is there in general, but with no specific example.

Q So there's no specific example or explanation of any test that could be used to determine whether something is electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.

A No such test is mentioned.

Q Does the '802 patent mention any test that can be used to determine whether a product forms a thin film when applied to the skin or tissue of nasal passages?

A The specification teaches as much.

Q And your position is that the specification teaches that the formulations form a thin film when applied to the skin. Correct?

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A Yes.

Q My question is a little bit different.

Does the '802 patent mention any type of test that can be used to determine whether a product forms a thin film when applied to the skin or tissue of nasal passages?

A No test is mentioned.

Q Does the '802 patent mention any type of test that can be used to determine whether the thin film electrostatically attracts particulate matter?

A No test is mentioned.

Q Does the '802 patent mention any type of test that can be used to determine whether the thin film holds particulate matter in place?

A No.

Q Does the '802 patent mention any type of test that can be used to determine whether the formulation provides adequate impermeability to the thin film?

A No such test is mentioned.

MS. PETERSON: Okay. We can take that exhibit down.

I'd like to mark next a copy of Mr. Haidri's responsive report. We'll mark this as Exhibit 33.

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A/V TECHNICIAN: Stand by.

(Exhibit 33 marked for identification and is attached to the transcript.)

MS. PETERSON: Maybe if you could scroll down to the bottom of the page so we can look at the entire first page. Yeah. Okay.

For the record, Exhibit 33 is a copy of plaintiff's expert report of -- I'm sorry. Mr. Haidri's responsive to -- let me start this over again. I didn't want to mispronounce your name.

Q Mr. Haidri, do you recognize Exhibit 33 as a copy of your responsive report that you prepared in this matter involving BlueWillow?

A Yeah, the first page, I recognize it.

Q Thank you.

MS. PETERSON: And then let's move to Page 87 of the PDF.

Q Mr. Haidri, is that your signature on the final page of the report?

A It is indeed.

Q And the report was signed and executed on August 12, 2022. Correct?

A Yes, correct.

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Q Now, Mr. Haidri, I did not see that you prepared a separate list of materials that you reviewed in forming your opinions.

Is that correct?

A A glossary? No, there's no glossary.

Q So would it be fair to say that the materials and documents and information that you considered in forming your opinions is all mentioned specifically within the report itself?

A Yeah, within its four corners.

MS. PETERSON: Could we go back to Page 2 of the report, which I believe is at Page 10 of the PDF.

Q And here on Page 2 of your report, Mr. Haidri, you have a list of your findings and conclusions. Correct?

A Yes, that's correct.

MR. KREMEN: Could you zoom in?

Mr. Haidri has eyesight problems.

THE WITNESS: Thank you.

A Okay. Go ahead.

Q So this list has a list of seven opinions that you have formed. Correct?

A All seven are not seen here. But, yes, that is correct.

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Q And so specifically the opinions that you formed are that the Amiji report did not make a clear and convincing showing that Claims 1, 2, 6, and 7 are invalid for each of the grounds that are listed in Items 1 through 7. Correct?
A Yes, that is true.
MS. PETERSON: Let's take a look at the next page, please.
Q And here in Section III of your report you have laid out what you have identified as the Relevant Patent Statutes. Correct?
A That is correct.
Q And these are the versions of 35 U.S.C. that you applied in forming your opinions.
Correct?
A Yes.
Q These are the versions of the patent statute known as the AIA version. Correct?
A That is correct.
Q So you did not consider the pre-AIA version of 35 U.S.C. when forming your opinions.
Correct?
A Correct. There was no substantial change.
MS. PETERSON: Let's go to the next page.

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Actually, I'm sorry, let's go to Section IV. So this is going to be Page 6 of your report, Page 14 of the PDF.
Q And here in Section IV, this is the beginning of some sections that contain the legal standards that you applied in forming your opinions. Correct?
A That is right.
Q So specifically Section IV has several pages concerning the clear and convincing standard of proof. Right?
A That is correct.
MS. PETERSON: And then let's move forward to Page 8 of the report. Yeah, that's good right there.
Q Now, in the first paragraph on Page 8 of your report, there is a discussion about the Wahi references that were cited during prosecution of the '802 patent. Correct?
A Yes.
Q And then looking at the second-to-last sentence of this paragraph, you state that, "These three references must be given special deference because they were considered by the USPTO prior to issuing a Notice of Allowance."

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Right?
A That is correct.
Q And then in the next sentence you state, "Under a clear and convincing standard, it is a finding of fact that should be overturned only upon a finding that no reasonable examiner would have allowed the claims in light of the considered prior art."
That's the standard that you applied in forming your opinions with respect to the Wahi patents?
Is that right?
A That is right.
Q I don't see that you've cited any case law or any other authority in support of that standard.
Where did you obtain that standard from?
A But it follows underneath, as you can see.
Q So it's based on the Microsoft Supreme Court decision?
A If you scroll down you will see more. But yes, Microsoft is the beginning.
Q So that language, "no reasonable examiner would have allowed the claims," you're basing that

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on the Microsoft case?
A Literally the words of the Supreme Court, yes.
Q Now, throughout these sections describing the legal standards that you applied, you contained -- or included a number of citations to the MPEP. Correct?
A That is right.
Q And that would be the Manual of Patent Examining Procedure that's used by the U.S. Patent and Trademark Office. Correct?
A That is correct.
Q Why did you include citations, and why did you rely on the MPEP in forming your opinions?
MR. KREMEN: Objection to the form of the question.
A Well, that is the guide for examiners to follow in issuing patents.
Q And is that the guide that a court or a jury follows when assessing the validity of a patent in litigation?
A It is entitled great deference under a case that is not mentioned here, but you will recall the name. It's called the Chevron deference.

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Q But you understand that the MPEP is not binding on courts. Correct?
A True enough, except that the Chevron deference applies, and the findings of an administrative agency are not likely overturned.
Q So that would apply -- what you're referring to as "Chevron deference," that would apply to the decisions of the examining agency. Correct?
A That is correct.
Q But the specific requirements of the MPEP, those are not bound -- or the courts are not bound by those. Right?
A They're entitled to deference, but not binding -- but not be binding.
Q And throughout these sections on legal standards, do you feel like you have appropriately cited the applicable legal authority for all of the standards that you've provided in your report?
A Well, I'm satisfied that there is the correct status of the law.
MS. PETERSON: Let's move forward to Page 9.
Q And you'll see here in Section V, now we have a section titled Standards For Inquiry Into

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Patent Invalidity. Correct?
A Yes.
Q And your first section is on Section 101?
A Yes, correct.
MS. PETERSON: Let's take a look at the next page. If we can focus, maybe go down just a little bit more. That looks good.
Q So here for Section 101, you've identified a two-step analysis. Correct?
A Yes.
Q And I see again you have a section of the MPEP cited, Section 2106. Right?
A That is correct.
Q Are those the PTO guidelines on subject matter eligibility?
A That is what I understand.
Q And these are the standards that you applied in forming your opinions. Correct?
A Yes.
MS. PETERSON: Okay. Let's move forward to Page 19 of the report. I think it's at Page 27 of the PDF. Yeah.
Q Here you have a Section D titled Rejections Based on Prior Art.
Why did you use the word "rejections"

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here?
A That is the language the PTO uses.
Q Okay.
A Any time a claim is disallowed, they say claims are rejected.
Q So that's the term that's used when the USPTO determines that an application under examination does not satisfy its requirements for patentability?
A Broadly speaking, yes.
MS. PETERSON: And then let's move forward another several pages to Page 23. Yeah. And we can focus there on the bottom.
Q Here you have a section addressing secondary considerations, and specifically commercial success. Correct?
A That is correct.
Q And this section sets out what you understand to be the controlling legal precedent with respect to secondary considerations?
A Yeah, more legal considerations. But they first were enunciated by the Supreme Court in Graham V John Deere. So the court of federal -- the CAFC is just repeating those considerations from the Graham case.

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Q And then if we go to the next page, I see you also have some references to requirements from the MPEP as well. Right?
A Yes.
MS. PETERSON: Let's go -- let's scroll down to the bottom of this page.
Q Section VI, this is a section that you have prepared addressing the person having ordinary skill in the art. Correct?
A That is correct.
MS. PETERSON: Let's go to the next page.
Q I see you have a case cited at the very top of this page. And we might need to go back up to the page before it.
But this case that you cite that addresses the proposition that, An incorrect determination as to level of skill or an incorrect finding may constitute reversible error if it influences the ultimate conclusion on obviousness.
Is that right?
A I see only that sentence, but ...
Q But you see on the next page, there's a case citation to Custom Accessories?
A Let me read this, please.
Q Yeah. Sure. Take your time.

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MR. KREMEN: Do you want to read above that?
THE WITNESS: That's what I meant, is being given to me all the text.
Q Yeah, if you need to move up and down, just let us know, we can do that.
A Okay. Now we are fine. So let me read this. Because I didn't want to answer your question out of context.
Q Sure.
A All right. Very good. Please.
Q So --
A Please repeat your question now.
Q Sure. So the key citation to custom accessories, that's with respect to the statement that immediately precedes it about an incorrect determination as to the level of skill. Correct?
A That is correct, yes.
MS. PETERSON: So I'd like to go down a little bit farther onto the next page. And, actually, can you -- yeah. Still at the top of the page, please. Yeah. That's great.
A Okay.
Q So the case -- or, sorry, the next sentence here at the top of Page 25 says, "Care

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must be taken not to select a person of extraordinary skill."
I don't see any case citation here.
What is that based on?
A It's based on a general practice in various judicial opinions about a person of ordinary skill in the art. Explicitly mentioned in Section 103 and implicitly in Section 112. So, anyway, that's where you can form that kind of an opinion with reasonable support in the statute and case law.
Q And what cases use that language, "extraordinary skill"?
A Well, there aren't any that I know of.
Q Let's scroll down. If we could look at the -- actually, you don't need to scroll down. But I'd like to look at the next paragraph right here on the screen.
Towards the bottom of that paragraph you state that, According to 112, he is the person who is able to make and use the claimed invention at the earliest filing date without undue experimentation.
Do you see that?
A Yes, I do.

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Q So that's your understanding of how the level of skill of a person of ordinary skill in the art should be set?
A Yes, it is my understanding, and I believe it's generally the case.
Q So a person of ordinary skill is going to be someone who can necessarily make and use the claimed invention without undue experimentation.
A Yes, correct.
Q And that's based on the language of 35 U.S.C. 112?
A 112 does not use the word "ordinary skill," just "personal skill in the art." But that is the usual understanding of the patent bar of the judiciary.
Q Could somebody be a person skilled in the art but still be unable to make the claimed invention without undue experimentation?
MR. KREMEN: Objection to the form of the question.
A Again, there will be no straightforward answer to your question. One or two individuals may not be able to, but generally a person of skill in the art should be able to.
Q But you agree that there may be

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circumstances where a person skilled in the art is not actually able to make and use the claimed invention without undue experimentation. Correct?
MR. KREMEN: Objection to the form of the question.
A Such a person would exist, I'm sure, statistically speaking, but that would be the exception, not the rule.
Q Well, would you agree with me that if the person skilled in the art is necessarily always able to make and use the claimed invention without undue experimentation, then we would never have any courts or juries finding patents invalid for lack of enablement?
MR. KREMEN: Objection to form.
A Once again, I don't understand the question. You have to repeat that slowly.
Q That's okay, I can skip it.
MS. PETERSON: Okay. Let's move ahead to Page 27. Actually, no, Page 26. And scroll down a little bit to the bottom.
Q This Section B titled The Level of Ordinary Skill, this contains your opinions regarding the level of ordinary skill in the art.
Correct?

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A Correct.
Q Did you discuss your understanding of the level of ordinary skill in the art with Dr. Lemmo while you were formulating your opinion?
A No, I did not consult Dr. Lemmo.
Q And did Dr. Lemmo consult you at any point in time about the level of ordinary skill in the art as it applies to the '802 patent?
A No, not in the context of this litigation.
Q Did Dr. Lemmo consult you at any point in time, for example in the Matrixx litigation, about the level of ordinary skill in the art?
A Yeah, that possibly happened, but I don't recall that.
Q Okay.
MS. PETERSON: I'm at a good breaking point. How about we go off the record now.
THE WITNESS: Thank you. I was going to ask --
VIDEO SPECIALIST: We are going off the record. The time is now 12:28 p.m.
(A recess was taken.)
VIDEO SPECIALIST: We're back on the record. The time is now 1:31 p.m.

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BY MS. PETERSON:
Q Mr. Haidri, did you have any conversations with anyone during any of the breaks of today's deposition about the substance of your testimony?
A No, I did not.
Q Okay. Thank you.
MS. PETERSON: Let's go back to Mr. Haidri's expert report, Exhibit 33. And I'd like to go to Page 45 of the PDF. And if you could scroll down to the last paragraph, please. Great.
Q Mr. Haidri, in the last paragraph on Page 37 of your report I see you refer to a Trutek product that was initially named NasalGuard MAPB.
Do you see that?
A Yes.
Q And you state it was formulated based upon the example formulations shown in the specification of the '802 patent. Correct?
A Yes, that is right.
Q What is the formulation of NasalGuard, do you know?
A Basically it contains the ingredients mentioned in the ten examples of the '802 patent. Most importantly, there's benzalkonium chloride, there's an adhesive film, and benzalkonium chloride also functions as a biocide.

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Q And is the actual formulation of NasalGuard -- which example -- sorry. Let me start over again.
Which of the ten tables in the '802 patent contains the formulation of NasalGuard, do you know?
A One of them does. I can't say which one.
Q And does the '802 patent identify the exact percentage of the ingredients in NasalGuard?
A Every one of this table provides ranges. None of them is an exact percentage of the active ingredients.
Q So none of the tables in the '802 patent specifically identify the precise percentages of the ingredients of NasalGuard. Correct?
A No, not an exact percentage. It's always a range.
Q And how do you know that the ingredients of NasalGuard are listed in one of the ten tables?
A I don't know that explicitly, but I've been told that the product being currently marketed does follow one of the examples.
Q And who were you told that by?

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A Mr. Kremen.
Q I'd like to move forward in your report to Page 49. That's fine right there.
So starting on Page 49 of your report, you have a section addressing written description. Correct?
A Enablement, yes.
Q But I'm talking about this particular section.
Is this Section D shown on Page 49 related to written description?
A Yes. I see that.
MS. PETERSON: And then let's move, let's scroll through this section until we get to Page 51. And if we go down, yeah, to look at that paragraph right there, that's great.
Q So in the second paragraph of Page 51, do you provide here in this paragraph an explanation of the applicable legal standard for written description?
A Let me read that.
All right. Go ahead.
Q So on Page 51 of your report, you set out the legal standard that you applied for written description stating that the written description

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requirement of 35 U.S.C. Section 112 (A) is that it must be complete enough as to enable a person of ordinary skill to make and use the invention. Correct?

A Yes.

Q And then you go on to say, "It does not need to teach the prior art to those who are unfamiliar with it." Correct?

A That is correct.

Q And so that's the standard that you applied in your written description analysis?

A Yes.

Q And then you go on to refer to a clinical study that you attached as Exhibit D to your report. Correct?

A Yes.

Q And did you rely on that clinical study report attached as Exhibit D as evidence of written description?

A Yes, you can say that.

Q Now, nothing from that clinical study was described in the '802 patent. Correct?

A Yes.

Q So yes, you agree with me that the '802

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patent does not contain any reference or any information from that clinical study. Right?

A I agree.

MS. PETERSON: Let's take this exhibit down. And I'd like to mark that clinical study report now. We'll mark that as Exhibit 34.

A/V TECHNICIAN: Stand by.

(Exhibit 34 marked for identification and is attached to the transcript.)

MR. KREMEN: What exhibit is that to his report?

MS. PETERSON: Exhibit D, as in dog.

MR. KREMEN: Thank you.

Q Okay. Mr. Haidri, do you recognize Exhibit 34 as a copy of the clinical study report that you had attached to your expert report as Exhibit D?

A That is the first page.

Q Okay. And we can scroll through it if you need to confirm the rest of the pages that you attached.

Would you like us to do that?

A Yes, please. Okay.

MS. PETERSON: Can you scroll down through to the end, please.

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Q So, Mr. Haidri, do you recognize Exhibit 34 as a copy of the clinical study report that you attached to your expert report as Exhibit D?

A Yes, I do.

MS. PETERSON: And if we could go back up to the second page of the report. One more page, then. There we go.

Q So on Page 3 of the clinical study report, do you see there is an objective of the study that is provided?

A Yes.

Q And the primary objective of the study was to evaluate the efficacy of MAPB nasal application gel in the prevention of the common cold and/or flu. Correct?

A That's what it says.

MS. PETERSON: And then if we could go to the next page?

Q And up here at the top you see there is a reference to Primary Endpoint?

MR. KREMEN: Where is that?

A Yes.

MR. KREMEN: I don't see it.

THE WITNESS: It is the second box -- or the fourth.

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MR. KREMEN: Oh, okay. Got it.

Q So the primary endpoint of this study was the percentage of subjects that were cold and/or flu-free in the treatment group at the end of the study as compared to the subjects who were cold and/or flu-free in the no-treatment group. Correct?

A Yes.

Q Would you agree with me that that endpoint that's provided here in the clinical study report, that's a subjective determination?

A Subjective, can't quite agree. But, all right. Overall, yes.

Q Now, the clinical study only assessed whether the subjects had either the common cold or the flu at the end of the study. Right?

A Yes.

Q The study did not evaluate the use of MAPB in any infections related to any other diseases. Correct?

I'm sorry, did you respond?

A I said "correct."

Q And is it also your opinion that this clinical study demonstrated that the ten formulations listed in the '802 patent work?

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A It does show that, yes.
Q Now, would you agree that the clinical study that we're looking at, it did not test whether NasalGuard electrostatically inhibits harmful particulate matter from infecting an individual?
MR. KREMEN: Objection to form.
A I did not quite follow this question. Where does electrostatic infection come in?
Q Well, that's what I'm wondering.
Did the clinical study test anything about the electrostatic attraction or electrostatic inhibition of NasalGuard?
A I don't think it's mentioned by name.
Q Did the clinical study test whether NasalGuard forms a thin film when applied to the skin or tissue of nasal passages?
A Is that a complete question? Can you please repeat that?
Q Is there anything in the clinical study report indicating that the investigators tested whether NasalGuard forms a thin film when applied to the skin or tissue of nasal passages?
A No, no such thing is mentioned.
Q Is there anything in the clinical study

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report indicating that the investigators tested whether a thin film electrostatically attracts particulate matter?
A It could have done, but the investigators don't say so.
Q So you don't see anything along those lines mentioned in the report. Correct?
A Not mentioned by name or explicitly.
Q Is there anything in the clinical study report indicating that the investigators tested whether a thin film holds the particulate matter in place?
A No. Subject to my qualification, the answer is no.
Q So there's no express reference to whether the investigators tested whether a thin film holds the particulate matter in place?
A Agreed.
Q So in other words, the clinical study report showed that fewer people in the treatment group had the cold or flu at the end of the study, but there's no discussion of why that was the case.
A No discussion, that is right.
MS. PETERSON: Okay. We can take that

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report down. And let's go back to Mr. Haidri's expert report, Exhibit 33.
And let me get you a page number.
I'd like to go to Page 78 of his report, which is maybe Page 86 of the document, 86 of the PDF. And if you could scroll down a little bit. That looks good.
Q In the second paragraph on Page 78 of your report you state that, Since 2012, approximately 7 million tubes of the '802 patented products have been sold worldwide.
Do you see that sentence?
A Yes.
Q What products specifically are you referring to?
A The NasalGuard product.
Q So that 7 million tubes refers to sales of all NasalGuard products?
A I will think so, or say so.
Q And where did you obtain that 7 million number from?
A From Mr. Kremen.
Q And if you could look a few sentences down in that same paragraph, do you see a sentence that starts with the word "satisfaction"?

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A Yes.
Q So you state in your report that, "Satisfaction is necessarily based on the ability of the product to inhibit harmful particles from infecting the purchaser through nasal inhalation."
Correct?
A Yes.
Q What did you do to analyze whether purchasers' satisfaction with NasalGuard was the result of the ability of the product to inhibit harmful particles from infecting the purchaser through nasal inhalation?
A From the large number of sales, which also implies repeat sales, repeat use by consumers, and the absence of any complaints.
Q Did you consider whether any customer satisfaction could be attributed to some other feature of the product?
A No consumer dissatisfaction has been brought to my attention.
Q No. I was asking you something a little bit different. Did you consider whether that customer satisfaction you're referring to, whether it could be attributed to some other feature of NasalGuard?

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A Well, I did not consider them, but I don't think it's particularly relevant.
Q Why not?
A Because there is only one function of this product and, obviously, the users are satisfied with it.
Q Is the product also intended to reduce the effects of seasonal allergies?
A As long as it contain negatively charge harmful particles, yes.
Q And would you consider allergies caused by pollen to be an infection?
A It is not an infection, but it can cause an allergy.
Q Did you consider whether any other attributes, for example the ability of the product to moisturize the skin?
A No, I did not.
MS. PETERSON: Okay. Well, Mr. Haidri, thank you so much for your time today. I actually don't have any other questions for you.
MR. KREMEN: Oh, okay.
THE WITNESS: Okay. Are we done?
MR. KREMEN: I don't have any others either.

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MS. PETERSON: Okay. So I think we're done. We can go off the record.
THE WITNESS: Thank you.
VIDEO SPECIALIST: All right. Just a moment, please.
This marks the end of the deposition of Amirali Haidri. We are going off the record. The time is now 1:54 p.m.
COURT REPORTER: Mr. Kremen, do you need a copy of the transcript?
MR. KREMEN: Yeah, I do. But in the regular course of -- I don't need an expedited copy. So but, yes, I do need a copy.
(Off the record at 1:54 p.m. EDT.)

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ACKNOWLEDGMENT OF DEPONENT

I, AMIRALI Y. HAIDRI, ESQUIRE, do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me, and any corrections appear on the attached Errata sheet signed by me.

_____ _____
(DATE) (SIGNATURE)

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CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Debra A. Whitehead, the officer before whom the foregoing proceedings were taken, do hereby certify that the foregoing transcript is a true and correct record of the proceedings; that said proceedings were taken by me stenographically and thereafter reduced to typewriting under my supervision; that reading and signing was not requested; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 7th day of November, 2022.

My commission expires:
April 30, 2023

E-NOTARY PUBLIC IN AND FOR THE STATE OF MARYLAND

EXHIBIT 9

TO BE FILED UNDER SEAL